vitamin C and vitamin E are present at 10 percent or more of the RDI per reference amount customarily consumed, and that 10 percent or more of the RDI for vitamin A is present as beta-carotene per reference amount customarily consumed.

4. Section 101.60 is amended by revising paragraph (c)(1)(iii)(A) to read as follows:

§ 101.60 Nutrient content claims for the calorie content of foods.

* * * * *

(c) * * *

(1) * * *

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, or, if a dietary supplement, it meets the definition in paragraph (b)(2) of this section for ''low calorie'' but is prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim; or

* * * * *

Dated: December 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–31194 Filed 12–27–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0245]

RIN 0910–AA59

Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations to require that dietary supplements be identified with the statement of identity ''Dietary Supplement'' on the principal display panel of the label and modify the nutrition labeling and ingredient labeling requirements for these foods. FDA is proposing these actions in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA). FDA is also responding to a citizen petition on type size requirements for these products.

DATES: Written comments by March 13, 1996; except that comments regarding information collection should be submitted by January 29, 1996, but not later than February 26, 1996. The agency is proposing that any final rule that may issue based upon this proposal become effective January 1, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Written comments regarding paperwork burden estimates should be sent to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5587.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the notable aspects of the 1990 amendments is that they added section 403(q) to the act (21 U.S.C. 343(q)). This section provided that most foods are misbranded unless they bear nutrition labeling.

In particular, section 403(q)(5)(F) of the act (originally section 403(q)(5)(E)) provided that if a food to which section 411 of the act (21 U.S.C. 350) applies (i.e., a dietary supplement of vitamins or minerals) contained any of the nutrients required to be listed in nutrition labeling, ''the label or labeling of such food shall comply with requirements of subparagraphs (1) and (2) [of section 403(q) of the act] in a manner which is appropriate for such food and which is specified in regulations of the Secretary.''

In response to this provision of the 1990 amendments, FDA published a proposal on nutrition labeling in the Federal Register of November 27, 1991 (56 FR 60366 at 60393). The document proposed, among other things, specific nutrition labeling requirements for dietary supplements of vitamins or minerals (proposed § 101.36) and to require that dietary supplements of herbs or other similar nutritional substances comply with the general regulation on nutrition labeling (§ 101.9) (21 CFR 101.9).

On October 6, 1992, the President signed into law the Dietary Supplement Act of 1992 (the DS act) (Pub. L. 102–571). In section 202(a)(1) (21 U.S.C. 343 note), the DS act established a moratorium until December 15, 1993, on the implementation of the 1990 amendments with respect to dietary supplements not in the form of conventional food. Section 202(a)(2) of the DS act required that the Secretary of Health and Human Services (the Secretary), and by delegation FDA, issue new proposed regulations applicable to dietary supplements no later than June 15, 1993, and final regulations by December 31, 1993.

In the Federal Register of January 6, 1993 (58 FR 2079), FDA published a final rule on the nutrition labeling of food in conventional food form (§ 101.9). Because of the DS act, however, this final rule did not cover the nutrition labeling of dietary supplements.

In the Federal Register of June 18, 1993 (58 FR 33715), FDA published a new proposed rule on the nutrition labeling of dietary supplements, as required by the DS act. FDA received over 400 responses to that proposed rule. In the Federal Register of January 4, 1994 (59 FR 354), FDA published a final rule (hereinafter referred to as ''the 1994 dietary supplement final rule'') based on the June 1993 proposed rule. Consistent with section 403(q)(5)(F) of the act, the 1994 dietary supplement final rule included separate nutrition labeling requirements for dietary supplements of vitamins or minerals, which are set out in § 101.36, and for dietary supplements of herbs and other nutritional substances, which the agency said were subject to § 101.9.

In the Federal Register of January 4, 1994 (59 FR 427), the agency proposed to expand the list of nutrients for which there are Reference Daily Intake (RDI) values in § 101.9(c)(8)(iv) to include vitamin K, selenium, chloride, manganese, fluoride, chromium, and molybdenum. The final rule based on that proposed rule is published elsewhere in this issue of the Federal Register.

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA, among other things, amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' in part, as a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or

combination of any of the previously mentioned ingredients (section 201(ff)(1) of the act). These ingredients are referred to in the provisions added to the act by the DSHEA, and in this document, as ''dietary ingredients.''

Additionally, the DSHEA amended section 403(q)(5)(F) of the act. While this section continues to provide that dietary supplement products shall comply with section 403 (q)(1) and (q)(2) of the act and provide nutrition labeling, it has been changed in a number of significant ways. First, it no longer distinguishes between supplements of vitamins and minerals and other dietary supplements. Second, it now contains specific provisions on: (1) The order in which dietary ingredients are to be listed in the nutrition information, (2) the listing of the quantity of each dietary ingredient, (3) the optional listing of the source of a dietary ingredient within the nutrition label, and (4) the listing of the other ingredients of the dietary supplement.

Given these changes in the law that requires that dietary supplements be nutrition labeled, changes in the regulations that FDA adopted to implement the 1990 amendments for dietary supplements are also necessary. In this document, the agency is proposing changes in its regulations that are necessary to reflect the changes that were enacted as part of the DSHEA. FDA's regulations were scheduled to go into effect on July 1, 1995. Given the need for these revisions, however, the agency has published notice of its intention not to enforce the regulations until after it has conformed its labeling regulations to the DSHEA, and industry has had an opportunity to relabel their products; that is, until after December 31, 1996 (60 FR 7711, February 9, 1995).

In this preamble, the agency will explain the proposed revisions to § 101.36 (21 CFR 101.36) and state which provisions of that regulation it is not proposing to change. The latter provisions will be discussed only to the extent necessary to understand how the revised provisions fit in the overall scheme on the nutrition labeling of dietary supplements. The agency seeks comments on the proposed changes to implement the DSHEA with respect to nutrition labeling. Although the codified section will be reproduced in its entirety, the agency urges those who comment to focus on the provisions in which changes are being proposed. Cooperation in this respect will hasten the publication of the final rule and thus maximize the time that industry will have to plan changes in its labeling.

II. The Term ''Dietary Supplement'' in the Statement of Identity

The DSHEA definition of ''dietary supplement'' provides, in part (section 201(ff)(2)(C) of the act), that such a product must be labeled as a dietary supplement. In addition, the DSHEA amended section 403 of the act by adding a new paragraph (s)(2)(B), which states that a food shall be deemed to be misbranded if it is a dietary supplement, and the label or labeling of the dietary supplement fails to identify the product by using the term ''dietary supplement,'' which term may be modified with the name of such an ingredient.

Thus, the label of a dietary supplement clearly must bear the term ''dietary supplement.'' However, no provision of the DSHEA explicitly addresses where on the food label identification with this term must appear. The Statement of Agreement on the bill that ultimately became the DSHEA states clearly that there is no legislative history for the DSHEA other than that agreement, and the agreement is silent with respect to where this term must appear (140 Congressional Record S14801 (October 7, 1994)).

It is a general rule of statutory construction that the act must be read as a whole. Thus, section 403(s)(2)(B) of the act, which states that the term must ''identify the product,'' must be read in conjunction with the other provisions of the act that address how food products are to be identified. These provisions, which have been in effect for many years, are section 403 (g)(2) and (i)(1) of the act. Section 403(g)(2) of the act, which pertains to a food for which a definition and standard of identity have been prescribed by regulation, provides that the food label must bear the name of the food specified in the definition and standard. Section 403(i)(1) of the act, which pertains to all other foods, provides that the food label must bear the common or usual name of the food, if any exists. Dietary supplements are labeled subject to the provisions of section 403(i)(1) of the act.

FDA has implemented section 403(g)(2) and (i)(1) of the act by adopting § 101.3 (21 CFR 101.3) on the identity of food in packaged form. This regulation states that the principal display panel of a food shall bear as one of its principal features a statement of the identity of the commodity (§ 101.3(a)). The regulation goes on in § 101.3(b) to state that the statement of identity shall be in terms of: (1) The name specified in or required by any applicable Federal law or regulation; or, in the absence thereof, (2) the common or usual name of the food; or, in the absence thereof, (3) an appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

When the requirement of section 403(s)(2)(B) of the act that the food be identified as a ''dietary supplement'' is read in conjunction with section 403(i)(1), which requires that the label of the food bear its common or usual name, that is, a statement that identifies the food (see § 102.5(a) (21 CFR 102.5(a))), it is clear that the term ''dietary supplement'' needs to appear as part of the common or usual name of any food that is to be marketed subject to the definition in section 201(ff) of the act. While under section 403(s)(2)(B) of this act this term may be modified with the name of a dietary ingredient, FDA tentatively concludes that the term ''dietary supplement'' must appear in the statement of identity of such products. To reflect this tentative conclusion, FDA is proposing to require in § 101.3(g) that when a food is marketed as a dietary supplement, its label shall bear the term ''dietary supplement'' as part of its statement of identity.

This proposed requirement is further supported by § 102.5 of FDA's regulations. This regulation sets out general principles for arriving at the common or usual name of a nonstandardized product, that is, a product that is not subject to a definition adopted under section 401 of the act (21 U.S.C. 341). Section 102.5(a) states in part:

> The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

Requiring that ''dietary supplement'' be included as part of the statement of identity of such foods is consistent with § 102.5 in several important respects. First, it will ensure that a term that accurately describes the basic nature of the food will appear prominently on the label of each dietary supplement. Second, it will ensure that there is consistency in the labeling of dietary supplements by requiring that they bear a consistent term. The agency stresses that the provisions of § 102.5 pertaining to uniformity of common or usual

names among all identical or similar products could be seriously compromised unless the term ''dietary supplement'' is included in the common or usual name of such a supplement. As explained below, the potential for compromising this requirement would be particularly great where dietary supplements are in other than tablet, capsule, powder, softgel, gelcap, or liquid form. Finally, use of this term as part of the statement of identity of dietary supplements will distinguish this potentially broad class of products from other types of food.

New section 201(ff)(2) of the act provides that a ''dietary supplement'' is a product that is not represented for use as a conventional food. At the same time, the DSHEA struck the provision that excluded products that simulate conventional foods from the coverage of section 411 of the act. (See section 3(c)(2) of the DSHEA.) As a result of the latter change, however, there may now be dietary supplements for which the presence of the term ''dietary supplement'' constitutes the primary, if not the only, means by which consumers will be able to determine that the food is a dietary supplement. Under such circumstances, it seems imperative that the term ''dietary supplement'' appear in the statement of identity.

For the foregoing reasons, FDA is proposing to add § 101.3(g), which states that products marketed as dietary supplements shall bear the term ''dietary supplement'' as part of their statement of identity, to its regulations.

III. Provisions of Proposed § 101.36

A. Foods Covered by § 101.36

The agency is proposing to revise § 101.36(a) to state that the label of a dietary supplement shall bear nutrition labeling in accordance with § 101.36, unless an exemption is provided for the product in § 101.36(h). Previously, only dietary supplements of vitamins and minerals were subject to the provisions of § 101.36. As stated above, dietary supplements of herbs and other similar nutritional substances were to follow the general nutrition labeling requirements in § 101.9. This separation was in accordance with section 403(q)(5)(F) of the act as passed in the 1990 amendments, which instructed the Secretary to issue nutrition labeling regulations appropriate for dietary supplements of vitamins and minerals.

However, the DSHEA revised 403(q)(5)(F) of the act to provide that it covers all dietary supplements, that is, all products that meet the definition in section 201(ff) of the act. Consequently, the agency is proposing to amend § 101.36(a) to reflect this change.

B. General Requirements

In § 101.36(b), the agency is proposing to require that nutrition information on dietary supplements include the information specified in this section of the regulations, and that it be presented in the format specified in proposed § 101.36(e). These proposed requirements reflect the requirements in section 403(q)(1) of the act and in section 2(b)(1)(A) of the 1990 amendments, which states that the information required under section 403(q) is to ''be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet.''

The agency notes that it has been asked whether current § 101.36(b) is to be interpreted as requiring nutrition labeling in all dietary supplement labeling (i.e., printed material accompanying a product) as well as on the label attached to a product. The agency advises that it does not intend that nutrition labeling appear on all labeling. It generally must appear on the label of dietary supplement products, although there may be circumstances in which it appears in labeling in lieu of the label. When nutrition labeling is presented, however, it must conform to the requirements of § 101.36.

C. Serving Size

Proposed § 101.36 (b)(1)(i) and (b)(1)(ii) on serving size and on servings per container, respectively, differ only slightly from current § 101.36 (b)(1) and (b)(2). In the first sentence of proposed § 101.36(b)(1)(i), the agency is stating that the subheading ''Serving Size'' is to be placed under the heading of ''Supplement Facts.'' The agency is proposing to include the name of the heading (i.e., ''Supplement Facts'') in § 101.36(b)(1)(i) for clarity.

On a related note, the agency points out that it is proposing to change the language in § 101.12(b), Table 2, to read ''Dietary supplements'' instead of ''Dietary supplements not in conventional food form'' in response to the DSHEA. The language in current § 101.12(b) reflected the DS act, which, in its legislative history, made clear that the moratorium it effected applied only to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances not in the form of conventional food. (See 138 Congressional Record S17240 (Joint Statement Senators Kennedy and Hatch) (October 7, 1992).) The DSHEA, however, evidences an intent, for labeling purposes, to treat all dietary supplements in a similar manner. In particular, section 7 of the DSHEA addresses dietary supplement labeling and does not distinguish between dietary supplements that are not in conventional food form and those that are. Therefore, FDA is proposing to amend § 101.12(b), Table 2, to reflect this development.

D. Requirements for Dietary Ingredients Having Recommendations for Daily Consumption

The DSHEA added four subclauses to section 403(q)(5)(F) of the act. Subclause (i) states that the Secretary (and, by delegation, FDA) shall provide by regulation that the nutrition information on dietary supplements first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation. The agency tentatively concludes that by a dietary ingredient ''for which a recommendation for daily consumption has been established by the Secretary,'' the DSHEA is referring to a nutrient having an RDI as established in § 101.9 (c)(7)(iii) and (c)(8)(iv) or a Daily Reference Value (DRV) as established in § 101.9 (c)(7)(iii) and (c)(9).

The requirement in section 403(q)(5)(F)(i) of the act that the dietary ingredients for which there are no RDI's or DRV's be listed in the nutrition label following the listing of dietary ingredients for which RDI's or DRV's have been established necessitates changes in the organization of § 101.36. The agency is therefore consolidating all of the information required in the listing of dietary ingredients for which RDI's or DRV's have been established under proposed § 101.36(b)(2) and the information required in the listing of other dietary ingredients in proposed § 101.36(b)(3). (See section III. E. of this document.)

1. Listing of Dietary Ingredients for Which RDI's and DRV's Have Been Established

With respect to the listing of dietary ingredients for which RDI's and DRV's have been established, the agency tentatively concludes that no major change in the 1994 dietary supplement final rule is needed as a result of the DSHEA. The agency is proposing in § 101.36(b)(2)(i) that the 14 nutrients

that, under § 101.9(c), must be listed in the nutrition labeling of a conventional food, when they are present, shall be listed in the nutrition label of a dietary supplement when they are present in the supplement in amounts greater than that that can be declared as zero under § 101.9(c). For clarity, the agency is identifying these nutrients by name in this proposed paragraph. This requirement is consistent with current § 101.36(b)(3), except that the current provision calls for ''a listing of all nutrients required in § 101.9(c),'' rather than specifying the name of each nutrient.

However, current § 101.36(b)(3) is silent on the subcomponents (e.g., polyunsaturated fat, soluble fiber, sugar alcohols) specified in § 101.9(c) that provide additional information about some of the nutrients required to be listed in the nutrition labeling of conventional foods. The listing of most subcomponents is voluntary under § 101.9(c). Generally, it is required only when claims are made. For example, the listing of soluble fiber is voluntary for conventional foods, except when a nutrient content claim is made about this nutrient. The agency did not require a listing of subcomponents in the 1994 dietary supplement final rule because it concluded that such labeling was not appropriate for such foods under section 403(q)(5)(F) of the act because that section applied only to dietary supplements of vitamins and minerals. Therefore, a fiber supplement, for example, did not come under the scope of supplement labeling.

Now, however, all dietary supplements, including products such as fiber supplements, are to be covered by the same nutrition labeling regulation (i.e., § 101.36). Therefore, the agency has tentatively concluded that it is appropriate to provide for the listing of the subcomponents specified in § 101.9(c). Accordingly, the agency is providing in proposed § 101.36(b)(2)(i) that calories from saturated fat and amounts of polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate may be declared in the nutrition label of dietary supplements and is proposing to require that they be declared when a claim is made about them.

There are other subcomponents of the nutrients that are required under § 101.9(c) to be listed in nutrition labeling that are not mentioned in that regulation (e.g., amino acids (subcomponents of protein), omega-3 fatty acids (subcomponents of fat)), and that may not be included in the nutrition label on conventional foods (see § 101.9(c)). However, because these subcomponents may be classified as dietary ingredients under section 201(ff)(1) of the act, manufacturers of dietary supplements may list them in the nutrition label under § 101.36. The difference in treatment of these subcomponents when they are present in dietary supplements as compared to when they are present in conventional foods creates the possibility of consumer confusion. To minimize this possibility, FDA is trying to retain as much consistency as possible between the nutrition labeling of conventional foods under § 101.9 and dietary supplements under § 101.36 (section 2(b)(1)(A) of the 1990 amendments). Thus, the agency is proposing that subcomponents that are not specified in § 101.9(c), e.g., individual amino acids, be listed under proposed § 101.36(b)(3) as dietary ingredients for which RDI's and DRV's have not been established.[1]

Among the 14 nutrients required to be listed in nutrition labeling of conventional foods are sodium, vitamin A, vitamin C, calcium, and iron. The other vitamins and minerals for which RDI's have been established in § 101.9(c)(8)(iv) are not required to be listed in the nutrition label of conventional foods except when they are added for the purpose of supplementation, or when a claim is made about them. (See § 101.9(c)(8)(ii).) The agency did not include this distinction among vitamins and minerals in the 1994 dietary supplement final rule because that rule pertained exclusively to supplements of vitamins and minerals. Because dietary supplements of vitamins and minerals are usually fabricated and, with few exceptions, contain only vitamins and minerals that are added for purposes of supplementation, the agency requires in current § 101.36(b)(3) that vitamins and minerals be listed whenever they are present in significant amounts.

Although the act, as amended by the DSHEA, requires that all dietary ingredients and their amounts be listed, the agency tentatively finds that requiring the listing of all vitamins and minerals with RDI's or DRV's that are present in herbal products, for example, would be unduly burdensome and in conflict with section 403(q)(1)(E) of the act, which requires the listing of vitamins and minerals only if the Secretary (and, by delegation, FDA) determines that such information will assist consumers in maintaining healthy dietary practices. In implementing the 1990 amendments, the agency made such a finding only for sodium, vitamin A, vitamin C, calcium, and iron (58 FR 2079 at 2106). Requiring all dietary ingredients in herbal products to be listed would necessitate extensive nutritional analyses of the vitamin and mineral content of all such products. While manufacturers are free to do so, FDA tentatively finds that it is unnecessary and inappropriate to require that such analyses be done. Thus, FDA tentatively concludes that, because the act must be read as a whole, and because section 403(q)(5)(F)(i) of the act must be read in conjunction with section 403(q)(1)(E) (in fact, it explicitly references that section), it is appropriate for the agency to follow the approach that it used in § 101.9 for conventional foods and to require the listings of vitamins and minerals (including potassium) other than sodium, vitamin A, vitamin C, calcium, and iron in the nutrition label of dietary supplements only when such other vitamins and minerals are added to the product for purposes of supplementation, or when a claim is made about them. Comments are requested on this tentative conclusion.

The agency observes that it did not clearly express in the 1994 dietary supplement final rule the amounts of vitamins and minerals that are not to be declared on the labels of dietary supplements because they are so small. Current § 101.36(b)(3) requires a listing of ''nutrients required in § 101.9(c) that are present in the dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in § 101.9(c),'' while § 101.9(c)(8)(iii) states that amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero. For clarity on what amounts do not have to be declared, the agency is proposing to include a statement in § 101.36(b)(2)(i) that amounts of vitamins and minerals corresponding to less than 2 percent of the RDI shall not be declared. The agency points out that this statement does not represent a change from the 1994 dietary supplement final rule but is merely a clarification of its provisions.

The agency notes that current § 101.36(b)(3) specifies that vitamin K, chloride, chromium, fluoride, manganese, molybdenum, and selenium shall be listed, when present. Because the agency has established RDI's for these nutrients (except for fluoride) (see the final rule on RDI's published

[1] To save space and to help the reader differentiate between these two types of dietary ingredients, the agency will refer to the dietary ingredients listed in proposed § 101.36(b)(2) as ''(b)(2)-dietary ingredients'' and to all other dietary ingredients as ''other dietary ingredients.''

elsewhere in this issue of the Federal Register), their listing is covered by the reference to all other vitamins or minerals listed in § 101.9(c)(8)(iv) in proposed § 101.36(b)(2). Accordingly, special mention of vitamin K, chloride, chromium, manganese, molybdenum, and selenium is no longer needed. Because FDA has not established an RDI for fluoride, if it is declared in nutrition labeling, under the proposed rule, it will have to be listed with the other dietary ingredients, as provided for in proposed § 101.36(b)(3).

FDA is also providing in proposed § 101.36(b)(2)(i) that protein not be declared in the nutrition label of dietary supplements that, other than ingredients added solely for technological reasons, contain only individual amino acids. While § 101.9(c)(7) allows protein content to be calculated as 6.25 times the nitrogen content of the food, the agency tentatively finds that it is misleading to declare the protein content in the nutrition label of a dietary supplement that contains free (individual) amino acids because protein, by definition, is composed of chains of amino acids connected together by peptide bonds. Such linkages are not found in products composed of free amino acids (Ref. 1, pp. 57 and 58).

The agency is proposing to require in § 101.36(b)(2)(i)(A) use of the heading ''Amount Per Serving,'' except that the agency is proposing to allow other appropriate headings when the serving size of the product is one unit. This aspect of the proposal is unchanged from what appeared in the 1994 dietary supplement final rule. The agency tentatively concludes that the proposed requirement is consistent with section 403(q)(1)(A) of the act, which provides that nutrition information is to be expressed on a ''per serving'' basis.

The agency notes that because it is proposing that quantitative amounts be presented in a separate column, rather than immediately following the listing of names as provided in the 1994 dietary supplement final rule, the agency is proposing that the heading may appear over the column of amounts rather than the column of names. The agency is proposing to provide flexibility in the placement of this heading because space constraints may make placement over the column of amounts impractical in some cases. Comments are requested on the placement of this heading.

The agency points out that, under current § 101.36(b)(3), the heading ''Amount Per Serving'' must be separated from the other information on the nutrition label by a bar above and beneath it. While the agency is proposing to carry forward this requirement, it is doing so in proposed § 101.36(e) on format. FDA will discuss this proposed requirement in more detail as part of its description of that paragraph.

The agency is proposing in § 101.36(b)(2)(i)(B) that (b)(2)-dietary ingredients be listed in a column on the left side of the nutrition label in the order and manner of indentation that is specified in that paragraph. No change in the order from current § 101.36(b)(3)(ii) is required as a result of the DSHEA, and FDA is not proposing to make any change.

The agency is addressing issues related to the column of names of (b)(2)-dietary ingredients in three paragraphs under proposed § 101.36(b)(2)(i)(B). Proposed § 101.36(b)(2)(i)(B)(*1*) specifies how calorie information is to be presented. The agency is proposing that, instead of listing calories above the column of names, they be listed first in the column of names, under a bar that separates the list from the heading ''Amount Per Serving.'' The agency tentatively concludes that giving calories prominence over other nutrients is not appropriate for supplements, which usually do not contain many calories. In addition, this change will save space. Proposed § 101.36(b)(2)(i)(B)(*1*) also requires that when ''Calories from fat'' or ''Calories from saturated fat'' are declared, they are to be indented beneath ''Calories'' in a manner similar to the indentation specified in § 101.9(d)(5).

Proposed § 101.36(b)(2)(i)(B)(*2*) specifies the synonyms that may be added in parentheses following the names of the (b)(2)-dietary ingredients. This paragraph is identical to the current regulation on synonyms in dietary supplement labeling (current § 101.36(b)(3)(v)), except that the agency is proposing to permit the use of ''folic acid'' as a synonym for folate. FDA recognizes that current regulations for nutrition labeling in §§ 101.9 and 101.36 do not include the term ''folic acid'' as an allowable synonym for folate. This omission was an oversight when FDA amended § 101.9 (58 FR 2079 at 2178) and issued § 101.36 (59 FR 373). Before the agency took these actions, § 101.9 had listed ''folic acid'' as the preferred term, with ''folacin'' as an allowable parenthetical synonym. When amendments to § 101.9 were initially proposed (55 FR 29847, July 19, 1990), the agency explained why the term ''folate'' was preferred to ''folacin.'' However, an explanation for the transition from ''folic acid'' to ''folate'' was inadvertently omitted, as was inclusion of the term ''folic acid'' as a synonym.

In light of common usage and FDA policy, and for consistency among the nutrition labeling and health claim regulations, the agency is proposing to correct § 101.36(b)(3)(v) to include ''folic acid'' as an allowable synonym for folate. The agency advises that it intends to revise § 101.9(c)(8)(v) to allow the listing of folic acid as a synonym for folate on conventional foods as well.

In proposed § 101.36(b)(2)(i)(B)(*3*), the agency provides that the percent of vitamin A that is present as beta-carotene may be declared immediately adjacent to or beneath the listing of vitamin A. This proposed provision essentially carries forward current § 101.36(b)(3)(iv). The agency tentatively finds that no change is needed in this provision as a result of the DSHEA, except that the agency is deleting the amount of vitamin A from the example given in this provision because, under this proposal, information on the quantity of each dietary ingredient will no longer appear immediately following the name but instead in a separate column.

2. Quantity of Each (b)(2)-Dietary Ingredient

The DSHEA added section 403(q)(5)(F)(ii) to the act. This section states that the listing of dietary ingredients shall include the quantity of each such ingredient (described in section 413(q)(5)(F)(i)), per serving, except that only the total quantity is required for proprietary blends, as discussed elsewhere in this preamble. Consistent with this section, the agency is proposing to require in § 101.36(b)(2)(ii) that the number of calories, if declared, and the quantitative amounts by weight of the (b)(2)-dietary ingredients be listed in a column to the right of the column of names. As previously discussed, this proposal differs from the 1994 dietary supplement final rule in that this information is to be listed in a separate column instead of immediately following the name of any dietary ingredient listed. The agency is proposing this change to allow space for information on the source of the dietary ingredient to be included immediately following the name, as discussed elsewhere in this document. The agency considered continuing to have the weight of the dietary ingredient placed immediately after the name of the dietary ingredient or its source but tentatively concluded that the wide variation in placement that could result when some dietary ingredients are listed

by name only, while others include the source ingredient, would make it difficult for some consumers to find the declaration of weight. Comments on this tentative conclusion, and on its possible impact on space requirements for the nutrition label, are requested.

The agency emphasizes that, consistent with the 1994 dietary supplement final rule (59 FR 354 at 360) and the DSHEA, the quantitative amount by weight declared for any dietary ingredient is to be the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient.[2] The agency points out that new section 403(s)(2)(A) of the act states that a dietary supplement is misbranded if its label or labeling fails to list, among other things, the ''name of each ingredient of the supplement that is described in section 201(ff)'' and the quantity of each such ingredient. The use of the word ''ingredient'' in section 403(s)(2)(A) of the act, instead of ''dietary ingredient,'' creates some ambiguity. However, the agency tentatively concludes that in this section the phrase ''that is described in section 201(ff)'' modifies the word ''ingredient'' rather than ''supplement.'' Thus, this provision is referring to a listing of the names and amounts of dietary ingredients. Accordingly, using the example of calcium carbonate, the weight of calcium would be declared, rather than the weight of calcium carbonate, the source of the dietary ingredient.

Section 403(s)(2)(A)(ii) of the act is also unclear on what basis the quantitative information should be reported (e.g., per dosage unit). The agency tentatively concludes that it is appropriate to require that this quantitative information be provided on a ''per serving'' basis because interpreting this provision in this way will mean that there need only be one list of the quantitative amounts of dietary ingredients in a supplement. Section 403(q)(5)(F) of the act also requires a list of dietary ingredients, but it specifies that the listing be on a ''per serving'' basis. If FDA were to interpret section 403(s)(2)(A)(ii) of the act differently, for example, to require information on a per dosage unit basis, it would mean that for dietary supplements whose serving size is two capsules, there would have to be two lists of dietary ingredient amounts on the label, one per capsule, the other per serving (two capsules). The agency tentatively concludes that such an interpretation would result in overcrowded labels with essentially redundant information. The agency recognizes, however, that the interpretation that it is proposing renders section 403(s)(2)(A) of the act somewhat redundant to section 403(q)(5)(F), and that the rules of statutory construction generally do not favor such a reading. Therefore, FDA specifically requests comments on the proposed interpretation.

In proposed § 101.36(b)(2)(ii)(A), the agency states that the declaration of quantitative amounts by weight shall be expressed using the increments specified in § 101.9(c)(1) through (c)(7), which includes increments for sodium and potassium. This proposed provision is carried forward from current § 101.36(b)(3)(i). As explained in the proposal of June 18, 1993 (58 FR 33715 at 33719), the agency was not aware of any reason for treating dietary supplements of vitamins and minerals any differently in this regard than conventional food. The agency is still unaware of any reason to modify this approach.

In proposed § 101.36(b)(2)(ii)(B), the agency states that the amounts of vitamins and minerals, excluding sodium and potassium, shall be the actual amounts present, using the units of measurement given in § 101.9(c)(8)(iv). The agency points out that in a final rule published elsewhere in this issue of the Federal Register entitled ''Food Labeling; Reference Daily Intakes,'' it is amending § 101.9 to change the units for biotin and folate to micrograms (mcg) and for calcium and phosphorus to milligrams (mg). The proposed specifications pertaining to the manner in which quantitative amounts by weight are to be declared simply carry forward those found in current § 101.36(b)(3)(i).

3. Declaration of Percent Daily Value for Each (b)(2)-Dietary Ingredient

In proposed § 101.36(b)(2)(iii), the agency is requiring that a percent Daily Value, where appropriate, be listed for the dietary ingredients declared under § 101.36(b)(2)(i), except that: (1) The percent for protein may be omitted as provided in § 101.9(c)(7) because the methods for analyzing protein are costly, and protein deficiency is not a public health concern in the United States; (2) no percent shall be given for the subcomponents for which DRV's have not been established (e.g., sugars) because it is not possible to calculate percent Daily Values when there are no DRV's; and (3) for the labels of dietary supplements that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, vitamin K, chloride, chromium, manganese, molybdenum, or selenium because RDI's or DRV's have not been established for these groups.

The agency points out that the exception for protein is carried forward from current § 101.36. The listing of no percent Daily Value for subcomponents is new in this proposal, but it is consistent with current § 101.36(b)(4) which states that ''no percent shall be given for sugars.'' As discussed previously, the agency did not address the listing of other subcomponents specified in § 101.9(c) because § 101.36 had applied only to dietary supplements of vitamins and minerals. Thus, the exception for these subcomponents was not needed because they were not declared.

The exception for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium on the labels of dietary supplements for use by infants, children less than 4 years of age, or pregnant or lactating women is new in this proposal and was omitted inadvertently in current § 101.36. Because DRV's are not established for these groups, percents of Daily Values cannot be calculated. Hence, the exception is needed.

Finally, the exception for vitamin K, chloride, chromium, manganese, molybdenum, and selenium for the population subgroups specified above is carried forward from current § 101.36. The agency points out that, in current § 101.36(b)(4), this exception had covered products intended for adults and children 4 or more years of age. Because the agency is adopting RDI's for these nutrients for adults and children 4 or more years of age in the final rule on RDI's published elsewhere in this issue of the Federal Register, this exception is no longer needed for products for that group.

The agency acknowledges that there are no RDI values codified for infants, children less than 4 years of age, or pregnant or lactating women for any of the vitamins and minerals. However, as explained in the 1994 dietary

[2] It is important to distinguish between the terms ''ingredient'' and ''dietary ingredient.'' The DSHEA uses the term ''dietary ingredient'' to refer to the primary substances to be listed in nutrition labeling, as opposed to ''ingredients'' that are the compounds used in the manufacture of the product. For instance, when calcium carbonate is an ingredient used to provide calcium in the manufacture of a dietary supplement, calcium is the ''dietary ingredient,'' and calcium carbonate is the ''ingredient,'' or, as specified in new section 403(q)(5)(F)(iii) of the act, the ''source of'' the dietary ingredient. Similarly, omega-3 fatty acids are ''dietary ingredients,'' while their source, fish liver oil, is the ''ingredient.'' (See section III., G. of this document for a further discussion.)

supplement final rule (58 FR 33721), FDA had intended to codify RDI values for these groups but did not in accordance with section 203 of the DS act, which provided that the agency could not adopt recommended daily values different from the values set forth in the agency regulation then in effect (§ 101.9(c)(7)(1992)) before November 8, 1993. To provide guidance to manufacturers in lieu of codifying values, the agency published label reference values for these groups in the preamble of the final rule on RDI's and DRV's on January 6, 1993 (58 FR 2206 at 2213). The agency encourages manufacturers to use these values for the labels of products intended for use by these groups. FDA intends to propose to codify RDI values for these groups in the near future for both the nutrients listed on the bottom of page 2213 of the final rule on RDI's and DRV's (58 FR 2206 at 2213) and the nutrients for which FDA is establishing RDI's for adults and children 4 or more years of age in the final rule published elsewhere in this issue of the Federal Register.

In proposed § 101.36(b)(2)(iii)(A), the agency is requiring that, when information on the percent of Daily Values is listed, the percentages be presented in a column on the right side of the nutrition label under the heading ''% Daily Value.'' This requirement is not different from what appears in current § 101.36(b)(4), except that the heading need not appear on a line lower than the heading ''Amount Per Serving.'' Current § 101.36(b)(4) provides for ''% Daily Value'' to appear below ''Amount Per Serving'' when calorie information is presented. Under this proposal, calorie information will go in the column of dietary ingredients. Therefore, FDA is proposing that ''Amount Per Serving'' and ''% Daily Value'' appear on the same line.

In proposed § 101.36(b)(2)(iii)(B), the agency set forth how the percent Daily Value is to be calculated. Although the agency is making no change in this calculation, it is rewording current § 101.36(b)(4)(i) to clarify that the actual amount is to be used in the calculation for vitamins and minerals (except for sodium and potassium), and that either the actual amount or the rounded amount may be used for other nutrients, e.g., fat. Under the proposed regulation, sodium and potassium are treated in the same manner as the other nutrients for which DRV's are established because § 101.9(c) provides for the declaration of their weight in rounded increments.

The agency is also rewording current § 101.36(b)(4)(ii), which it is carrying forward as proposed § 101.36(b)(2)(iii)(C), to make clear when ''Less than 1%'' (or ''<1%'') is to be used. Under proposed § 101.36(b)(2)(iii)(C), it is to be used to describe the percent Daily Value of a dietary ingredient when the dietary ingredient is present in an amount by weight that requires declaration (i.e., exceeds the amount that can be declared as zero), yet the amount is so small that the percent Daily Value when rounded to the nearest percent comes to ''0%.'' In place of ''0%,'' which might be confusing to consumers when a quantitative amount by weight is listed, ''Less than 1%'' is to be listed as the percent Daily Value for these substances. For example, for 1 gram (g) of total carbohydrate, the manufacturer could list ''Less than 1%'' as the percent of Daily Value.

As previously discussed, vitamins and minerals at less than 2 percent of the RDI shall not be declared, except that sodium and potassium can be listed at values less than 2 percent, consistent with § 101.9(c)(4) and (c)(5), respectively. Thus, proposed § 101.36(b)(2)(iii)(C), if adopted, will not apply to vitamins and minerals other than to sodium and potassium.

The agency is proposing that ''<1%'' may be used in place of ''Less than 1%'' to provide more flexibility when space is limited on the label. FDA did not provide for use of the symbol ''<'' for ''less than'' in regulations implementing the 1990 amendments because of concerns that a large number of persons would not understand its meaning. The agency has received numerous requests, however, to permit use of the symbol and is aware that it is being used on some nutrition labels with tight space constraints. FDA requests comments on the advisability of allowing use of the symbol ''<'' and the submission of any available data that would demonstrate consumers' comprehension of it. If the agency allows the symbol on nutrition labels of dietary supplements, it intends to provide for such use on conventional foods as well.

The agency points out that proposed § 101.36(b)(2)(iii)(D) through (F) parallel provisions in the current regulations. Proposed § 101.36(b)(2)(iii)(D) carries forward the requirement in current § 101.36(b)(4)(v) that the footnote ''Percent Daily Values are based on a 2,000 calorie diet'' be present when the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein. The agency is proposing to require that the symbol that refers to the footnote, when needed, immediately follow the value listed. For clarity, the agency is proposing to add to this provision that the footnote is to go below the last heavy bar required under proposed § 101.36(e)(6) and inside the box.

Consistent with current § 101.36(b)(4)(iii), in proposed § 101.36(b)(2)(iii)(E), the agency provides that the percent of Daily Value shall be based upon values for adults and children 4 or more years of age, unless the product is represented for one of the subgroups specified, in which case the column heading shall clearly state the intended subgroup. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns, as shown in the sample label in § 101.36(e)(10)(ii).

Finally, proposed § 101.36(b)(2)(iii)(F), consistent with current § 101.36(b)(4)(vi), requires the use of the footnote ''Daily Value not established'' for dietary ingredients that have no RDI's or DRV's and, therefore, for which a percent Daily Value cannot be calculated. Under this proposed rule, this footnote will apply to most subcomponents and, on labels of dietary supplements that are intended for use by infants, children less than 4 years of age, and pregnant and lactating women, to total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, vitamin K, chloride, chromium, manganese, molybdenum, or selenium. As previously explained, a final rule published elsewhere in this issue of the Federal Register establishes RDI values for vitamin K, chloride, chromium, manganese, molybdenum and selenium for adults and children 4 or more years of age, and, thus, percent Daily Values can now be calculated for those nutrients for that group. Therefore, the proposed footnote will have a more narrow application than under current § 101.36(b)(4)(vi). The agency points out that when both the footnotes ''Daily Value not established'' and ''Percent Daily Values are based on a 2,000 calorie diet'' are required, different symbols must be used to refer to each footnote so that consumers will not be confused.

Proposed § 101.36(b)(2)(iii)(G) is new and specifies that when calories, calories from fat, or calories from saturated fat are declared, the space under the ''% Daily Value'' column must be left blank for these items. This provision is necessary as a result of proposed § 101.36(b)(2)(i)(B)(*1*) that includes calories in the list of (b)(2)-dietary ingredients that are placed beneath the line in which the column headings, ''Amount Per Serving'' and ''% Daily Value,'' are specified. In nutrition labels of foods labeled in accordance with § 101.9, calories are

listed above the heading ''% Daily Value.''

In addition, proposed paragraph § 101.36(b)(2)(iii)(G) provides that the column ''% Daily Value'' may be omitted when there are no numerical values declared beneath it. For example, this situation will occur when only calories and protein are listed (a percent Daily Value cannot be calculated for calories in the absence of an RDI or DRV, and this declaration is optional for protein except as noted in § 101.9(c)(7)(i)), or when only calories or dietary ingredients subject to proposed § 101.36(b)(2)(iii)(F) are listed. Where the latter situation occurs, and the footnote ''Daily Value not established'' is required, the symbol (e.g., asterisk) must immediately follow the quantitative amount by weight for each dietary ingredient listed under ''Amount Per Serving.''

E. Requirements for Other Dietary Ingredients

The agency is proposing in § 101.36(b)(3) to prescribe how dietary ingredients that do not have RDI's or DRV's, and that are not subject to regulation under § 101.36(b)(2), are to be declared in the nutrition label when present in a dietary supplement. The agency is proposing this provision, which did not appear in the 1994 dietary supplement final rule, in response to section 403(q)(5)(F)(i) of the act, which was added by the DSHEA. As stated above, this provision states that the nutrition information on a dietary supplement shall first list those dietary ingredients for which RDI's or DRV's have been established and then list ''any other dietary ingredient present and identified as having no such recommendation'' (i.e., no RDI or DRV). As discussed earlier, to avoid confusion, the agency is proposing to refer to the latter group of dietary ingredients as ''other dietary ingredients.'' FDA is also proposing in § 101.36(b)(3) to set out how the quantitative amounts of these dietary ingredients are to be presented.

1. Names of Other Dietary Ingredients

The agency is proposing in § 101.36(b)(3)(i) that other dietary ingredients are to be listed in the nutrition label by their common or usual name in a column that is underneath the column of names of (b)(2)-dietary ingredients and the heavy bar described in proposed § 101.36(e)(6). The agency tentatively concludes that it is appropriate to list these names in a column because it is consistent with the format proposed for the listing of names of (b)(2)-dietary ingredients. Consistency makes the label more comprehensible to consumers. To enable consumers to distinguish between these two columns of dietary ingredients, the agency is proposing that they be separated by a heavy bar (see section H of this preamble on format specifications).

The agency considered specifying that the other dietary ingredients be listed in a particular order, such as alphabetical order or descending order of predominance by weight, to provide for a consistent theme in their presentation to assist consumers. Alphabetical order would have the advantage of being user friendly but would not be scientifically meaningful. Descending order of predominance by weight would be consistent with § 101.4 which specifies the order used in the ingredient statement on conventional foods. Because conventional foods are not required to declare the amounts of ingredients, this manner of listing gives consumers an indication of the relative amount of ingredients present. However, imposing this requirement on dietary supplements may be unnecessary because the amounts of the dietary ingredients (although not necessarily the ingredient sources of the dietary ingredients) are required to be listed in the nutrition label under section 403(q)(5)(F)(ii) of the act. Furthermore, such a listing would not necessarily reflect the relative biological activity of the dietary ingredients. Consequently, the agency has tentatively concluded that specifying a particular order is not justified. The agency requests comments on this issue.

The agency is proposing in § 101.36(b)(3)(i) that other dietary ingredients be listed by their common or usual name. This requirement is consistent with § 101.4 which requires that the ingredients of conventional foods be listed by common or usual name. To the extent that another dietary ingredient is covered by an official compendium, FDA would expect that the dietary ingredient's common or usual name to be drawn from that source (see section 403(s)(2)(D) of the act).

With regard to herbs and other botanicals, the agency encourages manufacturers to use common or usual names that are found in botanical data bases and that are widely used. Many of these names are part of our everyday language and are easily recognized by consumers. However, the agency realizes that arriving at an appropriate name for botanicals may be a problem because some plants have more than one common or usual name, or one name is used to describe many different species. In other cases, a particular species may not even have a common or usual name. Furthermore, the agency notes that uncertainty may exist as to which dietary ingredients are botanicals. For example, those in the trade may regard fungi (i.e., yeasts, molds, mushrooms) as ''botanicals,'' while a taxonomist may not (Ref. 2).

For the purposes of this regulation, the agency considers the term ''botanical'' as used in section 201(ff)(1)(C) of the act to include fungi and algae. While some questions may be raised about fungi, the agency believes there is general agreement that they are botanicals (Ref. 2). With respect to bacteria, the agency believes it is clear from both a botanical as well as a commercial viewpoint, they are not botanicals (Ref. 2).

2. Quantity of Other Dietary Ingredients

The agency is proposing in § 101.36(b)(3)(ii) that the quantitative amount by weight per serving of other dietary ingredients shall be presented in a column aligned to the right of the column of names and beneath the column of amounts described in proposed § 101.36(b)(2)(ii). The agency is proposing § 101.36(b)(3)(ii) in response to section 403(q)(5)(F)(ii) of the act, which was added by the DSHEA. This provision specifies that the listing of dietary ingredients shall include the quantity of each such ingredient per serving.

FDA is proposing to require that the quantitative amount listed in the nutrition label for a declared dietary ingredient be the total weight of that dietary ingredient and not the weight of a component of that dietary ingredient or of the source of that dietary ingredient. While a component of an ingredient may be listed as the dietary ingredient, under the proposed regulation, the name of that component ought to appear in the left column, and the weight of that component is what would be listed. For example, if a dietary supplement lists garlic as a dietary ingredient and makes no reference to a component of garlic, then the weight specified should be the weight of garlic. However, if the nutrition label lists allicin as the dietary ingredient, with garlic noted as the source ingredient, the weight specified should be the weight of allicin only. Liquid extracts of dietary ingredients are not to be treated any differently in that the weight specified should be the weight of the dietary ingredient listed that is in the extract and not include the weight of any solvent. The agency appreciates that such determinations may be difficult and seeks comments on this issue.

Manufacturers have the option of deciding what to list as a dietary ingredient (e.g., either garlic or the constituent, allicin). The agency is proposing this flexibility in accordance with section 201(ff) of the act, which provides, among other things, that a dietary ingredient may be a botanical or a constituent of a botanical. Thus, the agency is proposing that either the botanical or one or more constituents of a botanical may be declared as the dietary ingredient. The agency considered allowing manufacturers to declare both the botanical and one or more constituents as dietary ingredients within a single product, with the constituents of the botanical indented beneath the listing of the botanical. The quantitative amounts for the botanical and listed constituents would also be declared. This approach would possibly give consumers more information. However, the agency has tentatively rejected this approach because of concern that it would be potentially confusing to consumers who may not understand that the indented items are constituents of the nonindented dietary ingredient listed immediately above, or that the quantitative amounts of the constituents are also included in the quantitative amount of the nonindented dietary ingredient. The agency requests comments on whether it should consider allowing declaration of constituent information in the manner described above, whether there are alterative approaches to providing this type of information, and whether such flexibility is consistent with the DSHEA.

The agency notes that the DSHEA provides that dietary ingredients having RDI's or DRV's need be listed only when present in ''significant amounts.'' This limitation on listing in section 403(q)(5)(F)(i) of the act does not apply to other dietary ingredients, apparently because they do not have RDI's or DRV's, and, consequently, there is no basis for determining what constitutes a ''significant amount'' with respect to daily consumption. Hence, under the act, for other dietary ingredients there is no level below which declaration is not required.

In the absence of RDI's or DRV's, which are expressed in the units suitable for the declaration of nutrients in the nutrition label (i.e., mg for vitamin C), the agency is proposing to require that manufacturers express the amounts of other dietary ingredients in metric units that are appropriate. While it is not possible to specify appropriate units for every possible other dietary ingredient, for uniformity, FDA is proposing that any declaration of 1,000 or more units (mcg, mg, g) be declared in the next higher set of units (e.g., 1,100 mg should be declared as 1.1 g).

3. Symbol To Reflect Lack of Daily Value

In accordance with section 403(q)(5)(F)(i) of the act, which requires that other dietary ingredients be identified as having no recommendation for daily consumption, the agency is proposing in § 101.36(b)(3)(iii) that other dietary ingredients bear a symbol (e.g., an asterisk) in the column under the heading of ''% Daily Value'' that refers to another symbol placed at the bottom of the nutrition label that is followed by the statement ''Daily Value not established.'' When no dietary ingredients are declared in accordance with § 101.36(b)(2)(i), and the heading ''% Daily Value'' is not used, the agency is proposing that the symbol shall follow the declaration of the quantitative amount by weight for each other dietary ingredient listed. The agency considered placing the symbol elsewhere on the label (e.g., following the heading ''Amount Per Serving'' or with the name of each dietary ingredient) but tentatively concluded that it is most appropriate with the declaration of amounts because these values are used in the calculation of percent Daily Values when there are RDI's or DRV's.

The agency gave extensive consideration to the most appropriate wording for the statement to which the symbol refers. The agency considered a statement such as ''Not currently determined essential,'' which was suggested in a letter from a dietary supplement trade association (Ref. 3). The agency is unsure if such a statement would be more useful to consumers than the proposed statement, ''Daily Value not established,'' which is consistent with the statement used in current § 101.36(b)(4)(vi) and proposed § 101.36(b)(2)(iii)(F) for dietary ingredients without Daily Values. The agency requests comments on this issue.

F. Proprietary Blends

The agency is proposing in § 101.36(c) to provide for the listing of dietary ingredients in proprietary blends. New section 403(q)(5)(F)(ii) of the act provides that ''the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving.'' New section 403(s)(2)(A)(ii)(II) of the act contains a similar provision that requires ''the quantity of each such ingredient; or with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend.'' The ingredients referred to in this section are those in section 403(s)(2)(A)(i) of the act that are described in 201(ff), i.e., dietary ingredients. The agency notes that section 403(q)(5)(F)(ii) of the act specifies that the information is to be reported on a ''per serving'' basis. While section 403(s)(2)(A)(ii)(II) of the act does not specify any basis, FDA tentatively concludes, for the reasons set out in the earlier discussion of section 403(s)(2)(A)(ii) (see section III. D. 2. of this document) that the more specific instructions given in section 403(q), which directly addresses nutrition labeling and the listing of dietary ingredients, provide an appropriate basis for the declaration of the information required under section 403(s)(2)(A)(ii)(II) of the act.

Accordingly, the agency is proposing in § 101.36(c) to provide that a blend of dietary ingredients shall be identified by the term ''Proprietary Blend,'' which may be modified by an appropriate descriptive term or fanciful name (e.g., ''Proprietary Blend of Bioflavonoids''). To promote uniform presentation and, thereby, to minimize consumer confusion, FDA is proposing that the dietary ingredients in the proprietary blend be indented under the term ''Proprietary Blend'' (or a modification of this term) and be listed in a column or in a linear fashion.

The agency is proposing that the total weight of the dietary ingredients listed as components of the proprietary blend appear on the same line as the name of the blend, as illustrated in the sample label in § 101.36(e)(10)(v), to make it clear that the weight represents the total weight of the dietary ingredients listed. As previously explained, the manufacturer has the discretion to decide what to list as a dietary ingredient, e.g., whether to list garlic or a component of garlic, such as allicin. Regardless of what is considered to be the dietary ingredient, it is the weight of the dietary ingredient declared that is to be used in calculating the total weight of the blend.

Proposed § 101.36(c) also requires that the list of other dietary ingredients in a proprietary blend be given in order of predominance by weight since the weights of the individual dietary ingredients need not be specified (proposed § 101.36(c)(2)). The required listing by order of predominance by weight is consistent with ingredient labeling of conventional foods under § 101.4(a)(1) and is intended to give consumers an indication of the relative amounts of the other dietary ingredients present in the absence of information on their actual amounts.

All other requirements for the listing of dietary ingredients remain in effect for dietary supplements containing, or consisting solely of, a proprietary blend. For example, under proposed § 101.36(c)(3), the total weight must be specified to the right (beneath the column of amounts described in paragraph (b)(2)(ii) of § 101.36), and the symbol (e.g., asterisk) referring to the statement ''Daily Value not established'' must be placed in the column under the heading of ''% Daily Value,'' if present, or immediately following the quantitative amount by weight for the proprietary blend.

In addition, the agency is proposing to require that a dietary supplement containing a proprietary blend comply with § 101.36(b)(2) (§ 101.36(c)(1)). If the proprietary blend furnishes more than insignificant amounts of any required (b)(2)-dietary ingredients (i.e., calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, protein, vitamin A, vitamin C, calcium, iron, or any other dietary ingredient listed in proposed § 101.36(b)(2)(i) that is added for purposes of supplementation or about which claims are made), that dietary ingredient must be declared, as well as the amount of the ingredient and the percent of the Daily Value that the supplement supplies. While FDA recognizes some ambiguity in the language of section 403 (q)(5)(F)(ii) and (s)(2)(ii)(II) of the act, the agency tentatively concludes that an interpretation of these provisions of the act to mean that amounts of (b)(2)-dietary ingredients need not be listed individually, but rather be included in the total weight of the proprietary blend, would be inconsistent with section 403(q)(5)(F) of the act, which states that dietary supplement products ''shall comply with the requirements of subparagraphs (1) and (2),'' albeit in a manner which is appropriate for the product. Section 403(q)(1) and (q)(2) of the act require the listing of the individual nutrients determined by the Secretary to assist consumers in maintaining healthy dietary practices. FDA tentatively concludes that it would be contrary to the intent of the 1990 amendments to fail to list nutrients such as calories, total fat, sodium, or vitamin C, when present, in the nutrition labeling of dietary supplements containing proprietary blends.

Inasmuch as FDA is proposing that any (b)(2)-dietary ingredients present in the proprietary blend be listed in accordance with § 101.36(b)(2) (e.g., above the heavy bar separating (b)(2)-dietary ingredients and other dietary ingredients), these (b)(2)-dietary ingredients in the blend would not need to be listed a second time under the term ''Proprietary Blend'' and, if not listed, would not be included in the weight specified for such blend.

G. Information on the Source of a Dietary Ingredient and Other Ingredient Labeling Issues

In response to sections 403 (q)(5)(F)(iii) and (q)(5)(F)(iv) of the act, which were added by the DSHEA, FDA is proposing in new § 101.36(d) to allow the source of a dietary ingredient to be declared in the nutrition label. Section 403(q)(5)(F)(iii) of the act states that ''the listing of dietary ingredients may include the source of a dietary ingredient,'' and subclause (iv) states that ''the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.'' With respect to subclause (iv), the agency observes that it has received questions regarding the intent of the phrase ''except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.'' The agency acknowledges that the meaning of this phrase is not clear and has speculated whether the reference to ''subclause (i)'' is intended to refer to section 403(i) of the act. Given this ambiguity, the agency is interpreting subclause (iv) to mean that any ingredient listed in the nutrition label need not be listed a second time in the ingredient statement required in § 101.4. For example, under the agency's proposal, if an ingredient such as calcium carbonate is listed as the source of ''calcium'' in the nutrition information, it would not need to be listed again in the ingredient statement. Accordingly, the agency is proposing to revise § 101.4(a)(1) to provide that any ingredient of a dietary supplement that is listed in the nutrition label in accordance with proposed § 101.36(d) (i.e., inside the box) need not be repeated in the ingredient list.

The agency notes that one of the analyses of the DSHEA that it has received addressed section 403(q)(5)(F)(iv) of the act in detail (Ref. 4). The analysis stated: ''The listing [of dietary ingredients] can also include the source ingredient of the dietary ingredient, and the traditional ingredient declaration need not repeat those ingredients (although a technical correction is needed so that the first cross reference in section 403(q)(5)(F)(iv) of the act is to 'subsection (i)' rather than to 'subclause(i)').'' Hence, this analysis is suggesting the first cross reference is to section 403(i) of the act that deals with the ingredient statement that is required in § 101.4. This analysis is consistent with FDA's interpretation that: (1) A source ingredient may be included in the nutrition information, (2) the nutrition information must immediately precede the ingredient statement required in § 101.4, and (3) no ingredient listed in the nutrition label is required to be declared a second time in the ingredient statement.

Accordingly, the agency is proposing in § 101.36(d) that the source of any dietary ingredient (i.e., the ingredient supplying the dietary ingredient) may be added in parentheses immediately following or indented beneath the name of the dietary ingredient, and that the words ''as'' or ''from'' must precede the name of the source ingredient, e.g., ''calcium (as calcium carbonate)'' or ''calcium (from oyster shell powder).'' By way of exception, the agency is proposing that, if the name of the dietary ingredient (e.g., Siberian ginseng) or its synonym (e.g., ascorbic acid as a synonym for vitamin C) is itself the source ingredient, the listing of the dietary ingredient will fulfill the requirement for the listing of the ingredient. In regard to the use of the words ''as'' or ''from,'' many dietary supplements in the marketplace currently use such terminology. The agency tentatively concludes that these words will help to convey to consumers the understanding that such compounds are the source of the dietary ingredients.

If this proposal becomes final, when a source is disclosed in parentheses in the nutrition label, or when the name of a dietary ingredient or its synonym (e.g., ascorbic acid) is itself the source ingredient, the ingredient need not be listed in the ingredient statement that is required under section 403(i)(2) of the act. When a source is not identified within the nutrition label, proposed § 101.36(d) provides that it shall be listed in the ingredient statement in accordance with proposed § 101.4(g).

Under proposed § 101.4(g), the ingredient statement on a dietary supplement shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label. This provision is in accordance with section 403(q)(5)(F)(iv) of the act, which was added by the DSHEA. It requires that the nutrition information immediately precede the ingredient information. The agency tentatively concludes that when there is insufficient space below the nutrition label, it is appropriate to allow the

flexibility indicated and have the nutrition label precede the ingredient statement horizontally.

FDA is proposing in § 101.4(g) to require that the ingredient list be preceded by the word ''Ingredients,'' unless some ingredients (i.e., dietary ingredients or sources of dietary ingredients) are identified within the nutrition label, in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words ''Other Ingredients.'' FDA is proposing that the word ''Ingredients'' precede the list of ingredients so that the appearance of this aspect of the label is as consistent as possible with the labeling of other foods. As stated above, consistency in the presentation of food labeling information enhances consumer understanding. FDA is proposing that the term ''Other Ingredients'' be used to indicate to consumers that some ingredient information appears in the nutrition information that precedes the ingredient list.

Proposed § 101.4(g) also requires that ingredients that are not, or do not contain, dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, be listed in the ingredient statement. The agency acknowledges that a 1942 Trade Correspondence identified as TC-387 (Ref. 5) exempted ''excipients, fillers, binders, and other fabricating ingredients'' from complete ingredient declaration when used in manufacturing dietary supplements (i.e., labels could list ''excipients'' rather than listing excipients by name). As explained in the final rule on ingredient labeling (58 FR 2850 at 2869, January 6, 1993), however, although TC–387 has not been officially revoked, its position has been overturned by more recent agency statements of policy on this subject, as expressed in the Federal Register of August 2, 1973 (38 FR 20730), the Federal Register of March 16, 1979 (44 FR 16005), and in subsequent correspondence with industry (Refs. 6 and 7). These more recent statements of policy make it clear that the label for dietary supplements must contain a list of nutrients and a full statement of ingredients (except those exempted under section 403(i)(2) of the act), declared by their common or usual name. At this time, because TC–387 expresses a position contrary to the agency's policy since 1973, the agency is revoking TC–387.

In proposed § 101.36(d)(1), the agency is providing that source ingredients in dietary supplements be identified in accordance with § 101.4 that addresses ingredient labeling for all food products. A basic requirement of this section is that ingredients be listed by common or usual name (see § 101.4(a)). To help ensure correct identification of herbs or other botanicals, including algae and fungi, the agency is proposing in § 101.4(h)(1) that the botanical name in Latin binomial form be included in parentheses following the common or usual name. Proper scientific reference to a species is done with its Latin binomial, representing the genus in which the species has been placed and the species epithet, followed by the designation of the author or authors who published the name. When an author has moved a species from one genus to another, the name of the original author is enclosed in parentheses followed by the author who made the transfer. To ensure that there is consistency and clarity in declaration, the agency is proposing that any botanical name declared should be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature* (Ref. 8). The agency requests comments on this issue.

FDA recognizes that it is possible to have more than one acceptable botanical name in Latin form (i.e., a synonym). FDA advises manufacturers to choose the name that is most currently used in commerce and in appropriate references and, in cases of confusion, to consult with the agency.

Section 403(s)(2)(C) of the act, which was added by the DSHEA, provides that a dietary supplement is misbranded if it contains an herb or other botanical, and the label or labeling of the supplement fails to identify any part of the plant from which the dietary ingredient is derived. Accordingly, FDA is proposing in § 101.4(h)(2) that this information be provided as part of the required ingredient information. While nothing in the act requires that information on the part of the plant from which a botanical is derived be in a particular place on the label, FDA tentatively finds that it would be in the interest of consumers if the information were presented as part of the ingredient information because it would ensure that all the identifying information about the herb or other botanical (i.e., common or usual name, Latin binomial, and part of plant from which it is derived) is presented in one place.

FDA is proposing in § 101.4(h)(2) to require that the part or parts of the plant (e.g., leaf, flower, root, fruit, seed, or bark) be presented in parentheses immediately following the Latin binomial name of the botanical ingredient. This manner of presentation is consistent with the way other clarifying information is presented in ingredient statements (see § 101.4(d) and (e)). Whenever information on the part of the plant is presented on the label or in labeling, FDA is proposing to require that the name of the part of the plant be expressed in English. FDA tentatively concludes that pharmaceutical names such as ''flos'' for flower, ''radix'' for root, or ''fructus'' for fruit should not be used because they are not recognized in botanical nomenclature, and their meanings would not be commonly understood by American consumers. When an entire plant is used, the label should specify ''entire plant'' to meet the requirements of the act.

The requirements of proposed § 101.4(h)(1) and (2) apply whether the botanical ingredient is listed in an ingredient statement or in the nutrition label as provided by proposed § 101.36(d). However, inasmuch as section 403(i) of the act does not require ingredients to be listed when the food contains only one ingredient, FDA is proposing in § 101.36(h)(3) that for single-ingredient dietary supplements, the Latin binomial name and the part of the plant from which the dietary ingredient is derived may be prominently placed on the principal display panel or the information panel, or included in the nutrition label.

In proposed § 101.36(d)(2), the agency is requiring that when two or more sources are listed within a parentheses, they be listed in descending order by weight, which is consistent with the way ingredients are to be listed in § 101.4. This listing of ingredients in descending order by weight will provide consumers with an indication of the relative amount of each ingredient in the absence of information on their actual amounts. As discussed elsewhere in this preamble, the agency is not proposing that other dietary ingredients be listed in descending order by weight because the amounts of these dietary ingredients are required to be listed.

In proposed § 101.36(d)(3), the agency is providing that representations that a source ingredient conforms to an official compendium may be included such as by a reference to the compendium (e.g., ''Calcium (from calcium carbonate USP)''). This provision is consistent with the discussion in the preamble of the 1994 dietary supplement final rule that explained that the agency would not object to the use of the U.S.P. symbol in the ingredient list to identify those ingredients that are U.S.P. grade (59 FR 354 at 369), as long as the ingredients meet FDA's compliance requirements in § 101.9(g)(4), which are discussed below under *Compliance and*

Location Requirements. The agency recognizes that in some cases individual dietary ingredients may conform to compendial specifications even though the entire product does not. Thus, the agency is proposing in § 101.36(d)(3) to allow individual dietary ingredients to be so represented.

If such a representation is made, and the ingredient does not comply with the specifications of the official compendium, the supplement would be misbranded under 403(a) of the act. The agency notes that section 403(s)(2)(D) of the act provides that a dietary supplement is misbranded if it is represented as complying with an official compendium and fails to do so. Proposed § 101.36(d)(3) applies to representations about a particular ingredient and not the entire supplement, as does section 403(s)(2)(D) of the act.

H. Format Requirements

As stated above, the agency continues to believe that consistency in the presentation of nutrition information on all foods will help consumers observe and comprehend such information, as required by section 2(b)(1)(A) of the 1990 amendments. Accordingly, FDA is proposing in § 101.36(e) that the information required in proposed § 101.36 (b) and (c) be presented in a manner that is similar to the requirements listed in § 101.9(d) for conventional foods, as well as those in current § 101.36 for dietary supplements of vitamins and minerals. In this rulemaking, the agency is proposing to alter slightly the organization in current § 101.36 to combine all format requirements in proposed § 101.36(e), all exemptions in § 101.36(h), and all special labeling provisions (such as those for small or intermediate-sized containers) in § 101.36(i), respectively.

Despite the desire for consistency in the appearance of nutrition information on dietary supplements and conventional foods, the requirements adopted in the DSHEA, such as the listing of the names and amounts of other dietary ingredients and the optional listing of source information, necessitate that there be some differences in format. Accordingly, to signal to consumers that nutrition labeling on dietary supplements differs in several significant respects from that on conventional foods, FDA is proposing in § 101.36(e)(1) that the title for the nutrition information on packages of dietary supplements be ''Supplement Facts.'' The agency tentatively concludes that the title ''Supplement Facts'' and the proposed format structure are sufficiently similar to the title ''Nutrition Facts'' and the format requirements used in nutrition labeling of conventional foods for the consumer to immediately recognize that the information in the two boxes is related. However, by the use of a different name, the consumer can be taught to recognize the basic structural differences in nutrition information on the two different types of food products. For example, the nutrition information on dietary supplements will have the quantitative amounts by weight located in a separate column; may include source ingredients; and may not have a ''% Daily Value'' column if no dietary ingredients having RDI's or DRV's are present in the product. Comments are requested on the appropriateness of the title ''Supplement Facts.''

FDA is proposing in § 101.36 (e)(1) through (e)(3) to maintain the graphic requirements in current § 101.36(b) and (c)(1) through (c)(5). These sections require the use of the largest type size within the nutrition label for the title; bolding of the title and column headings; a hairline box around the nutrition label; a single easy-to-read type style; all black or one color type on a white or other neutral contrasting background, whenever practical; upper and lower case letters, except on very small packages; at least one point leading; and letters that do not touch. The agency is retaining these requirements because they are responsible, in large measure, for the appearance of the nutrition label and are designed to maximize the legibility of the label.

The agency is addressing type size requirements in proposed § 101.36(e)(4). Current § 101.36(c)(6) requires that: (1) packages with less than 12 square inches of total surface area available to bear labeling (i.e., small-sized packages) use a type size no smaller than 4.5 point for the nutrition label, (2) packages with 12 to 40 square inches of total surface area available to bear labeling (i.e., intermediate-sized packages) use a type size no smaller than 6 point, and (3) packages with more than 40 square inches of total surface area available to bear labeling use type size no smaller than 8 point, except that these larger packages could use 6 point type for column headings, footnotes, and information on beta-carotene, when present. Because the DSHEA does not necessitate any changes in type size, the agency is proposing in § 101.36(e)(4) to carry forward the requirement for larger-sized packages of 8 point type with 6 point type for column headings and footnotes. (The agency is not proposing to carry forward 6 point type for the information on beta-carotene because the agency tentatively concludes that the type size for all dietary ingredients should be uniform.) To be more consistent with the organization of § 101.9, FDA is proposing to move the exceptions in type size for small and intermediate-sized packages to § 101.36(i)(2). The agency will discuss these exceptions under section III.J. of this document.

Proposed § 101.36(e)(5) requires a hairline rule between the listing of each dietary ingredient. This requirement is identical to that in current § 101.36(c)(7). Following publication of the 1994 dietary supplement final rule, the agency received comment on this requirement and on the effect that the multiple hairlines could have on the legibility of labels of products with large numbers of dietary ingredients, where labels have severe space constraints, and where the minimum type size (i.e., 4.5 point type) is used. FDA requests comments on the use of hairlines to separate the dietary ingredients listed. Such comments will be particularly helpful if actual sample labels are included as well as suggestions for when relief from such a requirement should be provided, e.g., should hairlines be omitted when more than 8 (or some other number) dietary ingredients that qualify to use 4.5 point type are listed? Comments should set out in detail the basis for their recommendations.

Comments received by the agency since publication of the 1994 dietary supplement final rule suggest that there is some confusion about the relative size of bars used to separate parts of the nutrition label, and whether the bars are required by regulation. It appears that many persons were unable to find the regulatory references to the bars in current § 101.36 (b)(3), (b)(3)(ii), and (b)(4). Therefore, FDA is proposing to focus two paragraphs, § 101.36 (e)(6) and (e)(7), specifically on bars, rather than addressing them as ancillary issues in broader provisions. These paragraphs identify the points in the label format where bars are required and differentiate the thickness of the bars (i.e., ''heavy bars'' versus ''light bars'').

In proposed § 101.36(e)(6), the agency is requiring that a heavy bar be placed beneath the subheading ''Serving Size'' or the subheading ''Servings Per Container'' when it is required, beneath the last dietary ingredient to be listed in proposed § 101.36(b)(2)(i), and beneath the last other dietary ingredient to be listed in proposed § 101.36(b)(3). Also, in proposed § 101.36(e)(7), the agency is proposing that a light bar be placed beneath the headings ''Amount Per Serving'' and ''% Daily Value,'' which

will be above the listing of ''Calories,'' when the latter is required.

Except for the introduction in this rulemaking of a bar above, rather than below, the listing of ''Calories'' and of a bar to separate (b)(2)-dietary ingredients from other dietary ingredients, FDA is proposing no change from the bars as currently required above and beneath the ''Amount Per Serving'' heading in current § 101.36(b)(3) and at the bottom of the nutrition label in current § 101.36(b)(3)(ii). The use of the bars and their respective thickness is illustrated in sample labels under proposed § 101.36(e)(10).

For products that contain both (b)(2)-dietary ingredients and other dietary ingredients, the heavy bar that FDA is proposing to require in § 101.36(e)(6)(ii) beneath the last (b)(2)-dietary ingredient will result in a bar separating the list of (b)(2)-dietary ingredients from that of other dietary ingredients. FDA has tentatively concluded that this visual separation will assist consumers to differentiate dietary ingredients for which RDI's and DRV's have been established from other dietary ingredients for which such daily values have not been established.

The agency interprets the direction given in section 403(q)(5)(F)(i) of the act that ''nutrition information shall first list those dietary ingredients * * * for which a recommendation for daily consumption has been established * * * and shall list any other dietary ingredient present and identified as having no such recommendation'' as evidencing that such a differentiation should be made. FDA has tentatively concluded that the use of a heavy bar, similar to that which is used in § 101.9 to differentiate vitamins and minerals from preceding nutrients, will distinguish the two groups of dietary ingredients while helping to maintain some consistency in the appearance between nutrition labels on dietary supplements and products represented as conventional foods.

Proposed § 101.36(e)(8) addresses how nutrition information is to be presented on products that contain two or more separately packaged dietary supplements that differ from each other. This section, which allows manufacturers to choose between separate nutrition labels for each product or one aggregate nutrition label, is analogous to § 101.9(d)(13) for conventional foods and maintains the provisions of current § 101.36(b)(3)(iii), except that there is no longer a need to specify that separate columns be used to list quantitative amounts because the agency is proposing to require that the quantitative amounts on all dietary supplements be listed in separate columns.

Proposed § 101.36(e)(9), which encourages uniformity in presentation, and proposed § 101.36(e)(11), which allows for flexibility when there is insufficient continuous vertical space to accommodate the required components of the nutrition label, are identical to current § 101.36(c)(8) and (c)(10).

Proposed § 101.36(e)(10) provides sample labels to illustrate the format requirements of § 101.36.

I. Compliance and Location Requirements

FDA is proposing in § 101.36(f)(1) to provide that compliance with § 101.36 will be determined using the procedures outlined in § 101.9(g)(1) through (g)(8) for conventional foods. These regulations, which are cited in current § 101.36(d)(1), describe how FDA will collect samples for compliance reviews and the types of analytical methods that it will use, set quantitative criteria (e.g., allowable margins of error) for added and naturally occurring nutrients, and provide for the use of FDA-approved data bases.

An issue addressed in the preamble to the 1994 dietary supplement final rule was the requirement in § 101.9(g)(4)(i) for added vitamins, minerals, protein, dietary fiber, or potassium to be present in amounts ''at least equal to the value for that nutrient declared on the label'' (59 FR 354 at 369). A comment pointed out that U.S.P. monographs for several nutritional products require a minimum nutrient content of 90 percent of the label declaration, and that this specification was in conflict with FDA's requirement that added nutrients be present at 100 percent of declared value when tested during the shelf life of the product. In responding, the agency noted an inconsistency in U.S.P. directives in that the General Notices of the U.S.P. state that a dosage should be formulated to provide 100 percent of the labeled amount (Ref. 9).

In light of new section 403(s)(2)(D) of the act, the agency questioned whether it should alter its long-standing compliance criterion in § 101.9(g)(4)(i). The agency reviewed its response to the comment mentioned above and earlier correspondence from the agency to U.S.P. informing that organization that anything less than 100 percent of the value declared on the label for vitamin and mineral products is not acceptable, and that the only permissible deviation from this requirement would be a deviation that is attributable to the variability of the analytical method (Ref. 10).

The agency tentatively concludes that any deviation from the criterion in § 101.9(g)(4)(i) that is attributable to reasons other than variability of analytical methods would be a material fact and would need to be disclosed on the label if the agency were to allow less than 100 percent of the value declared. Accordingly, FDA has considered proposing that, on labels of products where U.S.P. specifications are met but less than 100 percent of the labeled amount is present, the U.S.P. designation would be allowed with a disclosure of the lack of the declared amount (e.g., a symbol by the U.S.P. designation that refers to a footnote that states ''May contain only ——% of the amount listed''). However, the agency is concerned that such a message could diminish consumer confidence in the values declared in nutrition labeling for all foods. Therefore, FDA tentatively concludes that its previous position is the better course of action (i.e., that, other than deviations that are attributable to the variability of the analytical method, anything less than 100 percent of the value declared on the label is not acceptable for added nutrients). Consequently, FDA is not proposing any change in its position that the requirements for the nutrients listed in § 101.9(g)(4) should pertain regardless of whether these nutrients are present in conventional foods or in dietary supplements.

Likewise, the agency is proposing in § 101.36(f)(1) that the criteria in § 101.9(g)(3) and (g)(4) are applicable to other dietary ingredients described in proposed § 101.36(b)(3)(i). The agency is unaware of any reason why these criteria that pertain to dietary ingredients that are nutrients should not apply to other dietary ingredients. Hence, the agency tentatively concludes that other dietary ingredients, when they are added, be present in amounts at least equal to the values declared in the nutrition label and, when they occur naturally, be present in amounts at least equal to 80 percent of the value declared. The agency is also proposing that reasonable excesses of other dietary ingredients over labeled amounts are acceptable within current good manufacturing practice, which is consistent with § 101.9(g)(6). The agency is unaware of any reason at this time for applying the approach in § 101.9(g)(5) to any other dietary ingredients. This section provides that food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if a composite of the product

is found to contain more than 20 percent in excess of the amount declared for one of these nutrients. FDA is not aware of any other dietary ingredient that should be singled out in this way. The agency requests comments on the proposed criteria for other dietary ingredients.

In recognition of the fact that the exemptive provisions referenced in proposed § 101.36(f)(1) may not include all situations in which nutrition information is technologically infeasible or impracticable on a particular package, the agency is proposing in § 101.36(f)(2) to carry forward current § 101.36(d)(2), which provides the opportunity in such a situation for firms to write to the Office of Food Labeling, FDA, to request additional exemptions or alternative means of compliance. This provision is identical to that in § 101.9(g)(9) for conventional foods. In such a situation, the firm should state why it is technologically infeasible or impracticable for the specified products to comply with the nutrition labeling regulations, identify alternative means of compliance that would be used to provide nutrition information for the product (e.g., specify type size variations needed), and explain why this mode of compliance would be consistent with the intent of the 1990 amendments and the DSHEA.

With respect to analytical procedures for compliance programs, § 101.9(g)(2) states that FDA will use methods as given in the ''Official Methods of Analysis of the AOAC [Association of Official Analytical Chemists] International'' unless no AOAC method is available or appropriate, in which case other reliable and appropriate analytical procedures will be used. AOAC methods and other reliable analytical methods exist for most vitamins and minerals used as, or as a component of, dietary supplements. However, AOAC methods do not exist for most other dietary ingredients, including many botanicals. Accordingly, the agency is interested in identifying a variety of analytical procedures and sources of information that can be used for other dietary ingredients. FDA requests comments on appropriate analytical procedures or other alternative approaches for determining whether the dietary supplement provides the quantity of dietary ingredient listed in the nutrition label for the supplement. Additionally, FDA is requesting information on organizations that establish such procedures.

The agency is proposing in § 101.36(g) to require that the location of nutrition information on a label be in compliance with § 101.2, except as provided in proposed paragraphs (i)(2) and (i)(5) of § 101.36. Proposed (i)(2) states that dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(13) for foods in small or intermediate-sized packages. Section 101.9(j)(13)(ii)(D) provides that foods in packages that have a total surface area available to bear labeling of 40 or less square inches may present the required nutrition information on any label panel. In addition, proposed (i)(5) states that dietary supplements are subject to the special labeling provision specified in § 101.9(j)(17) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information (see 50 FR 17202, April 5, 1995). Section 101.9(j)(17) allows the nutrition label on such packages to be moved to any other label panel that is readily seen by consumers. However, because of the requirement in section 403(q)(5)(F)(iv) of the act that the ingredient list immediately follow the nutrition label, proposed § 101.36(i)(5) states that the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g), which FDA has proposed to adopt in this document.

J. Exemptions and Special Labeling Provisions

FDA is proposing in § 101.36(h)(1) and (h)(2) to provide for small business exemptions in accordance with the 1990 amendments and the Nutrition Labeling and Education Act Amendments of 1993 (the 1993 amendments) (Pub. L. 103–80), which (1) stated that, after May 8, 1995, section 403(q)(5)(D) of the act, which provides an exemption based on total gross annual sales, shall apply to food from retailers only, and (2) established a new exemption for low-volume food products from manufacturers, packers, distributors, and retailers that are small businesses. A proposed rule to implement this change in § 101.9(j) and current § 101.36(f) was published on March 14, 1994 (59 FR 11872). A final rule has not yet been published.

To streamline the regulations and be consistent with the manner in which other exemptions and special labeling provisions are listed in current § 101.36(f) and (g) (proposed § 101.36(h) and (i)), FDA is proposing in § 101.36(h)(1) and (2) to cross reference the small business exemption in § 101.9(j)(1) and the exemption for low-volume food products of small businesses in proposed § 101.9(j)(18), respectively, rather than to independently codify those exemptions under § 101.36.

Proposed § 101.36(h)(3) incorporates the exemption in § 101.9(j)(9) for foods shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed. This exemption was incorrectly listed in current § 101.36(g) and identified as a special labeling condition. Inasmuch as nutrition labeling is not required on products shipped in bulk form that are not intended to be seen by consumers (section 403(q)(5)(A)(v)) of the act, it is being redesignated as an exemption under proposed § 101.36(h)(3).

Special labeling provisions (or conditions) are provided for specific situations in which the product is not exempt from nutrition labeling requirements, but deviations from the general nutrition labeling requirements are necessary for a variety of reasons. For example, proposed § 101.36(i)(1), which was carried forward from current § 101.36(g), references § 101.9(j)(5)(i) which describes a special labeling provision that pertains to the nutrition labeling of foods represented or purported to be for children less the 2 years of age. In the nutrition labeling of these foods, other than infant formula, the listing of calories from fat, calories from saturated fat, saturated fat, polysaturated fat, monounsaturated fat, and cholesterol is prohibited. FDA included this special labeling provision in its regulations to discourage the inappropriate application of adult dietary guidelines to infants and toddlers (55 FR 29487 at 29506, July 19, 1990, as modified in 58 FR 2079 at 2150). While current § 101.36(g) also cross references § 101.9(j)(5)(ii), which addresses broader issues of the format of nutrition labeling on foods intended for children less than 4 years of ages, these format issues are addressed elsewhere in this proposed regulation (e.g., the exclusion of percent Daily Value in proposed § 101.36(b)(2)(iii)(F) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber because DRV's have not been established for this age group). Accordingly, proposed § 101.36(i)(1) references only that portion of § 101.9(j)(5)(i) that prohibits the inclusion of calories from fat, calories from saturated fat, saturated fat,

polyunsaturated fat, monounsaturated fat, and cholesterol in the nutrition label of foods, other than infant formula, represented or purported to be for children less than 2 years of age.

Proposed § 101.36(i)(2) describes special labeling provisions for small and intermediate-sized containers. Special labeling provisions are provided for these containers in current § 101.36(g) which cross references § 101.9(j)(13). Section 101.9(j)(13)(i) allows small packages with less than 12 square inches of space available to bear labeling to supply an address or telephone number for the consumer's use in obtaining nutrition information in lieu of nutrition labeling when no claims or other nutrition information are present on the label or in labeling or advertising, or, if they are present, to provide the required nutrition information in 6 point type or in all upper case type of 1/16 inches minimum height. Section 101.9(j)(13)(ii) allows packages with 40 or less square inches of space available to bear labeling to present the nutrition label in a tabular format when the package shape and size cannot accommodate a standard vertical display and in a linear display if the label will not accommodate a tabular display; to use specified abbreviations; to shorten the required footnotes; and to place the required nutrition information on any label panel.

In addition to cross referencing these special labeling provisions, current § 101.36(c)(6) provides for smaller type size requirements for dietary supplements in small and intermediate-sized containers. That provision allows labels of dietary supplements in packages with less than 12 square inches of total surface area available to bear labeling to use a type size no smaller than 4.5 point in the nutrition label, in packages with 12 to 40 square inches of total surface area available to bear labeling to use a type size no smaller than 6 point, and in packages with more than 40 square inches of total surface area available to bear labeling to use type size no smaller than 8 point, except that these larger packages can use 6 point type for column headings, footnotes, and information on beta-carotene, when present.

In proposed § 101.36(i)(2), FDA is continuing to cross reference the special provisions in § 101.9(j)(13) and to allow the use of 4.5 point type on packages with less than 12 square inches of available label space and the use of 6 point type on packages with 12 to 40 square inches of available label space. However, in response to a citizen petition (Docket No. 94P–0110/CP1) (Ref. 11) from a trade association, the agency is proposing to provide additional flexibility for multi-ingredient dietary supplements in packages with less than 20 square inches of available label space. The petition stated that the majority of dietary supplement products on the market have labels that are 12 to 20 square inches in size, and that, while 6 point type in the nutrition label is feasible on single-nutrient products with this size label, there is insufficient space for all the required information on multinutrient products. The petitioner submitted sample labels in support of their position.

FDA is persuaded by this citizen petition that it is infeasible to use 6 point type on many products containing multiple dietary ingredients in packages with less than 20 square inches of space available to bear labeling. However, the agency tentatively finds that 6 point type is feasible on products with a limited number of dietary ingredients based on the following calculations. The agency calculates that a listing of 8 dietary ingredients in 6 point type plus one point leading between each name would take less than 1 inch of vertical space. Adding another inch to this for the title, headings, bars, and footnote would result in a nutrition label for a product declaring up to 8 dietary ingredients of no more, and possibly less, than 2 inches in height. Assuming a 1½ inch width, such a nutrition label would take no more than 3 square inches of surface area.

In the preamble to the final rule implementing the 1990 amendments, FDA based decisions on small package sizes on the assumption that not more than 30 percent of the total surface area of a package should be required to be devoted to FDA-required information that is not on the principal display panel (58 FR 2079 at 2155). On a package with 12 square inches of available label space, 30 percent of the total surface area is 3.6 square inches. Inasmuch as the ingredient list can be included in the nutrition label and based on the above calculations, the agency tentatively concludes that it is reasonable to require that 6 point type be used on a package with 12 to 20 square inches of space available to bear labeling when 8 or fewer dietary ingredients are listed. However, when a dietary supplement is in a package that has from 12 to 20 square inches of surface area available to bear labeling, and the nutrition label lists more than 8 dietary ingredients, the use of 6 point type would likely mean that more than 30 percent of the total surface area of the package would have to be devoted to FDA required information. Therefore, FDA is proposing in § 101.36(i)(2)(ii) to provide for the use of a smaller type size (i.e., a minimum of 4.5 point type) in such circumstances.

It should be noted that the dimensions used by the agency are inclusive of ''space available to bear labeling,'' not merely the dimensions of the current label. When there is space on the container to enlarge the current label (i.e., unused surface area available to bear labeling), and the current label is not large enough to provide the required information in accordance with format and type size specifications, FDA considers it is reasonable to expect that the manufacturer, packer, or distributor will increase the size of the label.

This action (i.e., proposing to allow only those products with more than eight dietary ingredients to use the smaller type size) is supported by the petitioner referred to above (Ref. 11), who stated in followup correspondence that, in a survey of its membership, ''responding companies agreed that eight or ten would be an appropriate cutoff number, triggering the smaller type size for multinutrient products,'' and that the responding companies believed that the cutoff should be set at eight nutrients (Ref. 12).

The aforementioned citizen petition (Ref. 11) also requested that § 101.2(c) be amended to allow the type size requirements in § 101.2 (c)(1) through (c)(3) to apply to the labeling of dietary supplements of vitamins and minerals. Current § 101.36 and proposed § 101.36 include type size requirements for varying sizes of packages of dietary supplements. Therefore, the agency is denying the request to have the type size requirements in § 101.2(c) pertain to the nutrition labeling of dietary supplements.

The agency notes that § 101.2 (c)(1) through (c)(3) were added to the regulations in 1974 (39 FR 15268), in part, in an effort to encourage manufacturers, packers, and distributors to include nutrition labeling on conventional foods. However, because the final rule on nutrition labeling (58 FR 2079) includes type size requirements, the agency believes there is no longer a need for § 101.2 (c)(1) through (c)(3) to address the type size of information in the nutrition label. The agency plans to amend § 101.2 (c)(1) through (c)(3) accordingly in a later document dealing with the labeling of conventional foods, as well as dietary supplements, so that the rulemaking will be seen by the greatest number of persons who may be affected by such action.

The agency is proposing, however, to amend § 101.2 (b) and (f) to include § 101.36 among the list of sections noted. Section 101.2(b) states that the information required to appear under the sections noted shall appear either on the principal display panel or the information panel unless otherwise specified by regulation. Section 101.2(f) provides that when the label of any package is too small to accommodate all of the information required under the sections noted, FDA may establish by regulation an acceptable alternative method of disseminating such information to the public (e.g., by the use of smaller type size).

FDA is proposing a special labeling provision in proposed § 101.36(i)(2)(iii) for dietary supplements in packages that have a surface area available to bear labeling of 40 or less square inches. Under this provision, when the nutrition label on packages of this size is presented on a label panel other than the principal display or information panels, as allowed in § 101.9(j)(13)(ii)(D), the ingredient information must move in conjunction with the nutrition label. This provision is in response to section 403(q)(5)(F)(iv) of the act as added by the DSHEA, which states that nutrition information shall immediately precede the ingredient information.

In proposed § 101.36(i)(2)(iv), the agency is providing additional flexibility for dietary supplements in packages that have a surface area available to bear labeling of 40 or less square inches. When it is not possible for primary (inner) containers of this size to comply with the type size requirements, the agency is proposing that type as small as needed may be used in the nutrition label as long as the primary container is securely enclosed in outer packaging that bears nutrition labeling in required type size. In the preamble of the 1994 dietary supplement final rule (59 FR 354 at 367), the agency erroneously advised that it considered outer packaging that securely encloses a primary container and that is not intended to be separated from the primary container under conditions of retail sale to be the equivalent of the product label. In these situations, the agency stated that manufacturers did not have to repeat the nutrition information on the primary container, although it encouraged them to do so to give consumers easy access to the information once the container is removed from the outer packaging. These statements were inconsistent with section 201(k) of the act which defines the term ''label'' as ''* * * a display of written, printed, or graphic matter upon the immediate container of any article * * *'' as well as with previous agency policy that requires that other required information appear on the primary container (e.g., statement of identity, quantity of contents, name and place of business of the manufacturer, packer, or distributor). Therefore, nutrition labeling is required to appear on the label of the primary container. However, consistent with FDA's intent in the preamble of the 1994 dietary supplement final rule to allow flexibility, the agency is proposing in § 101.36(i)(2)(iv) that when nutrition labeling is presented in required type size on outer packaging that securely encloses a primary container and is not intended to be separated from the primary container under conditions of retail sale, the nutrition labeling on the primary container may use type size as small as needed to accommodate all of the required information on the label.

FDA is proposing to carry forward the special labeling provisions in current § 101.36(g) for foods in multiunit containers in proposed § 101.36(i)(3) and for foods sold in bulk containers in proposed § 101.36(i)(4).

FDA is proposing to add a special labeling provision in proposed § 101.36(i)(5) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information. This provision cross references § 101.9(j)(17), which was recently added to the regulations (60 FR 17202, April 5, 1995) and allows the nutrition label on such packages to be placed on any alternate panel that can be readily seen by consumers. However, as previously discussed, ingredient information must move in conjunction with the nutrition label. Accordingly, proposed § 101.36(i)(5) includes an exception to § 101.9(j)(17) whereby the ingredient list would continue to be located immediately beneath the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as proposed in § 101.4(g).

K. Misbranding Provisions

Current § 101.36(h), redesignated as § 101.36(j) in this proposed rulemaking, cross references the misbranding provisions of § 101.9(k) that were first proposed in the Federal Register of March 30, 1972 (37 FR 6493) and that were issued and published in the Federal Register of January 19, 1973 (38 FR 2125). These provisions were based on findings of fact and conclusions of law resulting from 1968–1970 Special Dietary Hearings (38 FR 2143). Following a comment period, these regulations were modified and published as final regulations in § 1.17 (i)(2) through (i)(6) on March 14, 1973 (38 FR 6961). In the reorganization and republication of Title 21 of the Code of Federal Regulations that appeared in the Federal Register of March 15, 1977 (42 FR 14308), § 1.17(i) was recodified as § 101.9(i).

No changes were made to the original codified language of the subject paragraphs until regulations implementing the 1990 amendments were published on January 6, 1993, at which time FDA redesignated the paragraphs as § 101.9(k) and modified § 101.9(k)(1) to incorporate a reference to the general requirements for health claims in §§ 101.14 and 101.9(k)(5) in response to requests to remove restrictions about the incorporation of substances such as rutin, inositol, and other similar substances to conventional foods or dietary supplements (38 FR 2478 at 2502 and 38 FR 2079 at 2166, respectively).

The current misbranding provisions in § 101.9(k) state that a food will be considered to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies: (1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom except as provided for in health claim regulations; (2) that a balanced diet of ordinary foods cannot supply adequate amounts of nutrients; (3) that the lack of optimum nutritive quality of a food, by reason of the soil on which the food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the diet; (4) that the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the diet; (5) that the food has special dietary properties when such properties are of no significant value or need in human nutrition; and (6) that a natural vitamin in a food is superior to an added or synthetic vitamin or to differentiate in any way between vitamins naturally present from those added.

FDA has reviewed these misbranding provisions in light of the DSHEA and current scientific knowledge. As a result of its review, the agency is proposing to delete current § 101.9 (k)(2) and (k)(5). Section 101.9(k)(2) states that a food is misbranded if its label or labeling represents, suggests, or implies that a

balanced diet of ordinary foods cannot supply adequate amounts of nutrients. The agency is deleting this provision based on the acknowledgment by scientific and consensus groups that there are certain situations in which the use of dietary supplements may be needed for persons to obtain adequate nutrient intakes. For example, the National Academy of Sciences has stated in the 10th edition of ''Recommended Dietary Allowances'' that ''In a few cases where deficiency is commonly observed (e.g., iron deficiency in women), food fortification and individual supplementation are appropriate'' (Ref. 13, p. 14). Also, the ''Dietary Guidelines for Americans'' states that supplements may be needed by pregnant or lactating women; other women in their childbearing years; people who are unable to be active and eat little food; and people, especially older people, who take medicines that interact with nutrients (Ref. 14). These conclusions are supported by other documents such as ''Diet and Health, Implications for Reducing Chronic Disease Risk'' (Ref. 15, pp. 509–525) and a task force representing the American Dietetic Association, National Council Against Health Fraud, Inc., Society for Nutrition Education, American Society for Clinical Nutrition, and the American Institute of Nutrition (Ref. 16).

Section 101.9(k)(5) states that a food is misbranded if its label or labeling represents, suggests, or implies that ''the food has dietary properties when such properties are of no significant value or need in human nutrition.'' New section 403(r)(6) of the act, which was added by the DSHEA, provides for statements that, in part, describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or which describe general well-being from consumption of a nutrient or dietary ingredient. There is no requirement in this new section that the subject of the statement be of significant value or need in human nutrition. Therefore, to eliminate any inconsistency between section 403(r)(6) of the act and the agency's regulations, FDA is proposing to delete § 101.9(k)(5). If it adopts the proposed deletion of § 101.9 (k)(2) and (k)(5), the agency will redesignate current § 101.9(k)(3) as (k)(2), § 101.9(k)(4) as (k)(3), and § 101.9(k)(6) as (k)(4).

FDA is not aware of grounds for eliminating the other provisions under § 101.9(k). However, if information is provided in comments to this proposed rule that persuades the agency that the findings of fact and conclusions of law resulting from 1968–1970 special dietary hearings (38 FR 2143) that underlie the other provisions in § 101.9(k) are no longer supportable, FDA will consider deleting the subject provisions in the final rule.

IV. Conforming Amendments

As previously discussed (in section III.J. of this document), FDA is proposing to amend § 101.2 (b) and (f) to include § 101.36 in the lists of sections noted. The agency is also proposing to amend § 101.2(d)(1), which states that all required label information shall appear on the principal display panel or the information panel. This paragraph was recently amended in a document entitled ''Food Labeling; Placement of the Nutrition Label on Food Packages'' (60 FR 17202, April 5, 1995) to exclude from its coverage products that are exempt under § 101.9(j)(13), which allows flexibility in the placement of the nutrition label on packages that have less than 40 square inches of space available to bear labeling, and § 101.9(j)(17), which allows the nutrition label on packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information to be placed on any alternate panel that can be readily seen by consumers. Inasmuch as proposed § 101.36 (i)(2) and (i)(5) cross reference § 101.9 (j)(13) and (j)(17), respectively, and therefore similarly exclude dietary supplements that meet the criteria in § 101.9 (j)(13) and (j)(17) from coverage of § 101.2(d)(1), FDA is proposing to amend that paragraph to cite § 101.36 (i)(2) and (i)(5) as exceptions.

Section 101.9(j)(6) of the nutrition labeling regulations lists as an exemption: Dietary supplements of vitamins and minerals that have an RDI as established in § 101.9(c)(8)(iv) of this section or a DRV as established in § 101.9(c)(9) of this section shall be labeled in compliance with § 101.36, except that dietary supplements of vitamins and minerals in food in conventional form (e.g., a breakfast cereals), of herbs, and of other similar nutritional substances shall conform to the labeling of this section.

As discussed previously (in section III. of this document), the definition of dietary supplements in new section 201(ff) of the act broadens the coverage of proposed § 101.36 and eliminates differentiation based on the form of the food. Therefore, FDA is proposing to amend § 101.9(j)(6) to exempt all dietary supplements from coverage under § 101.9, noting that such foods must be labeled in compliance with § 101.36.

The agency is also proposing to amend § 101.65(b)(4) to modify the example given of the statement of identity of a dietary supplement of vitamin C to incorporate the term ''dietary supplement'' in accordance with proposed § 101.3(g). The amended paragraph will state:

> A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., ''corn oil,'' ''oat bran,'' ''dietary supplement of vitamin C 60 mg tablet'').

V. Regulatory Review Under Executive Order 12866

This proposed rule has been deemed by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget to be a significant regulatory action pursuant to Section 3(f)(4) of Executive Order 12866 because it raises novel legal and/or policy issues arising out of a legal mandate, namely the DSHEA, or principles set forth in Executive Order 12866. Accordingly, this proposed rule has been formally reviewed by OIRA pursuant to the provisions of Executive Order 12866.

VI. Economic Impact

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this proposed rule is not an economically significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

There are several different types of products that may be considered to be dietary supplements. These products include, but are not limited to, vitamin and mineral supplements, herbal products, and products that contain other similar nutritional substances. Estimates of the number of such products range from 4,000 to over 25,000 such products. Similarly, estimates of the number of dietary supplement manufacturers range from 150 to 600.

A. Costs

Categories of costs for relabeling include administrative, analytical, printing, inventory disposal, and reformulation. The administrative costs associated with a labeling regulation result from the incremental administrative labor expended in order to comply with it. The administrative activities that FDA anticipates will be undertaken in response to a change in regulation include: Identifying the underlying policy of the regulation, interpreting that policy relative to a firm's products, determining the scope and coverage related to product labels, establishing a corporate position, formulating a method for compliance, and managing the compliance method. Longer compliance periods decrease administrative costs because firm executives often delegate downward decisions that are less immediate. Many firms estimate that administrative effort would be twice as high for a 6-month compliance period as for a 12- month compliance period (Ref. 17). FDA is proposing that any final rule that may issue based upon this proposal become effective January 1, 1997. This effective date leads to a compliance period of approximately 1 year. FDA estimates that for a 1-year compliance period, manufacturers of dietary supplements will incur administrative costs of $425 per firm for each of between 150 and 600 firms, or a total of between approximately $65,000 and $300,000.

FDA requests comments on whether dietary supplement products will undergo analytical testing as a result of these regulations if implemented as proposed. Dietary supplement products need only list those nutrients present in significant amounts. The agency assumes that manufacturers of vitamin and mineral supplements are already aware of the nutritional content of their products, and that those products will not undergo any additional testing. However, it is possible that herbal and other botanical products may undergo additional testing for their nutritional content. The agency estimates that between 4,000 and 20,000 products may undergo testing once every 5 years for a total discounted analytical cost over the next 20 years of between $8.3 and $41 million (7 percent discount rate).

However, many herbs do not contain significant amounts of the nutrients that must be listed in the nutrition label, and this fact may be determinable from reference works without testing. Thus, some herbal and botanical products may not require nutrient testing at all. FDA requests comments on this issue.

FDA estimates that printing/redesign costs for dietary supplement manufacturers would be approximately $1,000 per label for each of 75,000 labels with a 6-month compliance period, or a total of $75 million. However, the length of the compliance period determines a firm's ability to combine planned label changes with mandated changes. Therefore, incremental labeling and redesign activities are less costly with lengthier compliance periods. With the proposed compliance period of 1 year, printing and redesign costs would be approximately half that of a 6-month compliance period, or approximately $37.5 million.

FDA estimates the cost of inventory disposal associated with a 1-year compliance period to be approximately $13 million. However, manufacturers of these products have been aware of the potential for regulated labeling changes due to recent regulatory and legal activities. FDA assumes that the majority of these manufacturers have been taking the necessary steps to reduce their label inventories since January of 1994, the date of publication of FDA's previous regulations regarding the labeling of dietary supplements. Therefore, the cost of inventory disposal is more accurately calculated on a compliance period of 2 years, or approximately $6.5 million.

FDA has examined the impact of the proposed regulations on dietary supplement manufacturers and has determined that administrative costs would be between $65,000 and $300,000, discounted analytical testing costs would be between $8.3 and $41 million over the next 20 years (7 percent discount rate), printing and redesign costs would be $37.5 million, and inventory disposal costs would be $6.5 million. Therefore, total discounted costs are estimated to be between $52 and $85 million.

B. Benefits

According to Congress as stated in the DSHEA, almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition. Although almost all dietary supplements of vitamins and minerals currently contain substantial nutrition information, many other dietary supplements do not typically provide such information. Moreover, the information that is presented is not presented in any particular order or following any particular format.

This proposed regulation will benefit consumers by ensuring that adequate and complete nutrition information is provided accurately and consistently in order to aid consumers in their dietary choices. As consumers are given more informative labeling in an improved format, uncertainty and ignorance concerning the ingredient and nutrient content of the products they consume will decrease, and some consumers may select more nutritious, healthier products. Moreover, since FDA began its food labeling initiative in 1989, a theme that has been consistently sounded is that consumers will benefit from nutrition labeling that is presented in a consistent manner, not only within a particular product class but also across all foods. Such a consistent manner will not only help to make the information presented more comprehensible but will facilitate comparisons among food products. This proposed rule, if adopted, will help to ensure that dietary supplements are nutrition labeled in a manner that is as consistent as possible with other foods, yet, with such features as the listing of substances for which no daily reference amount has been established, in a manner that is fully tailored to the special nature of those products.

All told, this action, if adopted, will benefit consumers by ensuring that nutrition labeling is provided on dietary supplements in a manner that will help consumers to follow healthy dietary practices.

C. Regulatory Flexibility

According to the Regulatory Flexibility Act, the definition of small business is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For most food processing industries, a business is considered small if it has fewer than 500 employees. For dietary supplements, a business is considered small if it has fewer than 750 employees. FDA estimates that the majority of manufacturers of dietary supplements meet the SBA definition of a small business.

The agency has published an exemption from mandatory nutrition labeling for small businesses in § 101.9(j)(1) (incorporated in this proposed rule in § 101.36(h)(1)) and has proposed an exemption for low-volume food products of small businesses in § 101.9(j)(18) (59 FR 11872, March 14, 1994) (incorporated in this proposed rule in § 101.36(h)(2)). As of the date this subject rulemaking is proposed to become effective, January 1, 1997,

§ 101.9(j)(1) (and proposed § 101.36(h)(1)) will only apply to retailers. Proposed § 101.9(j)(18) (and proposed § 101.36(h)(2)) will apply to manufacturers, packers, distributors, or retailers of low volume products, defined as fewer than 200,000 units, produced by firms with fewer than 200 employees. As of May 1997, criteria for meeting the definition of low volume product will be reduced to 100,000 units and 100 employees. FDA does not have information to show how many dietary supplement products would be exempted under this provision. The agency believes that several herbal and botanical products will have unit sales and firm size low enough to meet this definition. Therefore, many of the products produced by businesses defined as small by the SBA will not be subject to the rules if issued as proposed.

The agency requests information regarding the impact of this regulation on small firms. Most of the costs associated with labeling regulations are fixed costs which are typically more burdensome for small firms than for large firms because of the smaller sales base on which to spread costs. Estimates of annual sales for the dietary supplement industry range from $2.9 billion to over $4 billion. The estimated cost of between $52 and $85 million is approximately one to three percent of industry annual sales. In relation to the volume of sales, this amount does not appear to represent a significant cost.

D. Summary

Total discounted costs of this regulation is estimated to be between $52 and $85 million over the next 20 years (7 percent discount rate). These costs include administrative, analytical, printing, and inventory disposal costs. The benefits are improved and more consistent information with which consumers can refine their choices for health or other reasons. FDA is unable to quantify this benefit.

FDA has analyzed the costs and benefits of this proposed rule and has determined that it does not constitute an economically significant rule as defined by Executive Order 12866.

FDA has also analyzed the impacts on small firms according to the Regulatory Flexibility Act and has determined that the proposed rules will probably not have an adverse impact on a substantial number of small businesses. Nonetheless, the agency requests comments on the impact on small businesses and any burden-reducing options.

VII. Environmental Impact

The agency has determined under § 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). In particular, the proposed regulations would require that manufacturers and distributors of dietary supplements disclose information on the levels of specific nutrients on the label or in labeling of their products with some exceptions. Additionally, the proposed regulations would require that these firms disclose the quantity of other dietary ingredients in their dietary supplements. Therefore, in accordance with 5 CFR Part 1320, FDA is providing below the title, description, and respondent descriptions for the information collection requirements that will be submitted to OMB along with an estimate of the annual collection of information burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering necessary information, and disclosure of the information.

FDA is soliciting comments to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) evaluate the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, when appropriate.

Title: Requirements for Nutrition and Ingredient Labeling of Dietary Supplements.

Description: The proposed rule, § 101.36, would require that most dietary supplements provide on their labels and in their labeling information on the quantity of specific nutrients present in them, along with daily value for each, and the quantity of other dietary ingredients. This requirement is being proposed to implement the requirements of the 1990 amendments and the DSHEA.

The DSHEA requires that dietary supplements provide information on their labels as to the level of nutrients and other dietary ingredients present in them. The DSHEA requires that FDA issue regulations to implement these requirements within specific timeframes. Section 101.36(b)(2) specifies the nutrients for which amount must be present on the labels of dietary supplements and § 101.36(b)(3) provides for the listing of the quantity of other dietary ingredients, respectively. Other paragraphs of § 101.36 provide information to assist manufacturers and distributors of dietary supplements to determine the amount of nutrient that their products contain and that should be disclosed on the labels of the products.

Description of Respondents: Persons and businesses, including small businesses.

Title 21	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total annual hours	Total operating maintenance costs
101.36	600	40	24,000	4	96,000	$51,616,000

FDA estimates that each supplier of dietary supplements will revise the labels for each product that is not otherwise exempt to comply with the requirements for nutrition labeling within the first year after publication of a final rule. The agency expects that the number of respondents and corresponding annual burden hours will decrease over succeeding years because it does not believe that firms will modify the composition of each of their products and revise the labeling for each of their products each year. FDA has estimated the total annual operating and

maintenance costs of $51,616,000 based on maximum estimated relabeling costs of $34 million, all of which will be incurred in the first year; annualized analytical costs of $13.2 million; and labor and overhead costs of $4.616 million for the first year. The agency believes that these costs will decrease significantly over succeeding years. The agency does not believe that this proposed regulation requires capital costs on the part of respondents.

The agency has submitted copies of the proposed rule to OMB for its review of these requirements. Interested persons are requested to send comments regarding information collection by Janaury 29, 1996, but not later than February 26, 1996 to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

IX. Effective Date

FDA is proposing to make this regulation effective on January 1, 1997. This date is consistent with section 7(e) of the DSHEA, which states that dietary supplements must be labeled in accordance with its provisions after December 31, 1996.

X. Comments

Interested persons may, on or before March 13, 1996 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Lehninger, A. L., ''*Biochemistry*,'' Second Edition, pp. 57–58, Worth Publishers, Inc., New York, NY, 1977.

2. Memorandum of telephone conversation between Mr. Mark Blumenthal, American Botanical Council, and Susan Thompson, FDA, March 16, 1995.

3. Bass, I. S., A. L. Young, and S. C. Stolzer, Piper & Marbury, letter to F. E. Scarbrough, January 31, 1995.

4. Covington & Burling, ''Dietary Supplement Health and Education Act of 1994,'' October 12, 1994.

5. FDA trade correspondence letter (387), June 23, 1942.

6. FDA opinion letter, Taylor M. Quinn, Office of Compliance, Bureau of Foods, to Stanley Skelskie, March 30, 1979.

7. FDA opinion letter, Taylor M. Quinn, Office of Compliance, Bureau of Foods, to Stanley Skelskie, January 25, 1980.

8. Greuter, W., editor (chairperson), *International Code of Botanical Nomenclature (Tokyo Code) Adopted by the 15th International Botanical Congress*, Koeltz Scientific Books, D–61453 Konigstein, Germany, 1994.

9. U. S. Pharmacopeial Convention, Inc. *USP XXII, NF XVII, The United States Pharmacopeia*, The National Formulary, General Notices and Requirements Applying to Standards, Test, Assays, and Other Specifications of the United States Pharmacopeia, pp. 1 to 3, January 1, 1990.

10. Tanner, J. T., letter to V. Srinivasan, U.S. Pharmacopeial Convention, Inc., May 7, 1991.

11. Citizen Petition, Docket No. 94P–0110/CP1.

12. Dickinson, Annette, Council for Responsible Nutrition, Letter to Susan Thompson, FDA, February 28, 1995.

13. Subcommittee on the 10th Edition of the RDA's, Food and Nutrition Board, Commission of Life Sciences, National Research Council, ''Recommended Dietary Allowances, 10th Ed.,'' p. 14, Washington, DC, National Academy Press, 1989.

14. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Nutrition and Your Health, Dietary Guidelines for Americans,'' Home and Garden Bulletin No. 232, U.S. Government Printing Office, Washington DC, 1990.

15. Committee on Diet and Health, Food and Nutrition Board, Commission of Life Sciences, National Research Council, ''Diet and Health, Implications for Reducing Chronic Disease Risk,'' Chapter 18, Dietary Supplements, National Academy Press, Washington, DC, 1989.

16. ''Recommendations concerning supplement usage: ADA statement,'' *Journal of the American Dietetic Association*, 87:1742–3, 1987.

17. Center for Economics Research, ''Compliance Costs of Food Labeling Regulations Final Report,'' prepared under FDA Contract No. 223–87–2097, Washington, DC, FDA, DHHS, 1991.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

1. Section 101.2 is amended by revising paragraphs (b), (d)(1), and (f) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(b) All information required to appear on the label of any package of food pursuant to §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

* * * * *

(d)(1) Except as provided by § 101.9(j)(13) and (j)(17) and § 101.36(i)(2) and (i)(5), all information required to appear on the principal display panel or on the information panel under this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as provided by § 101.9(j)(17) and § 101.36(i)(5), any vignettes, designs, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required under any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted under part 10 of this chapter.

2. Section 101.3 is amended by adding new paragraph (g) to read as follows:

§ 101.3 Identity labeling of food in packaged form.

* * * * *

(g) When a food is marketed as a dietary supplement, the label shall bear the term ''dietary supplement'' as a part of the statement of identity in

conformance with the provisions of paragraph (d) of this section.

3. Section 101.4 is amended by revising paragraph (a)(1) and adding new paragraphs (g) and (h) to read as follows:

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

* * * * *

(g) When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word ''Ingredients,'' unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with § 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words ''Other Ingredients.'' Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be immediately followed by parenthetical statements of:

(1) The Latin binomial name of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature,* and shall include the designation of the author or authors who published the Latin name, when appropriate; and

(2) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., ''Garlic (*Allium sativum* L.) (bulb)''), except that this designation is not required for algae. The name of the part of the plant shall be expressed in English (e.g., ''flower'' rather than ''flos'').

(3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the required identification of the Latin binomial name and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

4. Section 101.9 is amended by revising paragraph (j)(6), by removing paragraphs (k)(2) and (k)(5), and by redesignating paragraphs (k)(3), (k)(4), and (k)(6) as (k)(2), (k)(3), and (k)(4), respectively, to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(j) * * *

(6) Dietary supplements, except that such foods shall be labeled in compliance with § 101.36.

* * * * *

5. Section 101.12 is amended in paragraph (b), Table 2, by revising the entry ''Dietary supplements not in conventional food form'' under the subheading ''Miscellaneous category'' to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1,2,3,4]

Product category	Reference amount	Label statement [5]
*	*	*
Miscellaneous Category—		
*	*	*
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonsful, etc.	_____ tablet(s) _____ capsule(s), ____ packet(s), tsp(s) (_____g), etc.
*	*	*

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e, heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

* * * * *

6. Section 101.36 is revised to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

(a) The label of a dietary supplement shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (h) of this section.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the subheadings and the format specified in paragraph (e) of this section.

(1) *Serving size.* (i) The subheading ''Serving Size'' shall be placed under the heading ''Supplement Facts'' and aligned on the left side of the nutrition label. The serving size shall be determined in accordance with §§ 101.9(b) and 101.12(b), Table 2. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as ''tablets,'' ''capsules,'' ''packets,'' or ''teaspoonfuls.''

(ii) The subheading ''Servings Per Container'' shall be placed under the subheading ''Serving Size'' and aligned on the left side of the nutrition label, except that this information need not be provided when it is stated in the net quantity of contents declaration.

(2) *Information on dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in § 101.9(c) and their subcomponents (hereinafter referred to as ''(b)(2)-dietary ingredients'').*

(i) The (b)(2)-dietary ingredients to be declared, that is, total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c). Calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate may be declared, but they shall be declared when a claim is made about them. Any other vitamins or minerals listed in § 101.9(c)(8)(iv) or in § 101.9(c)(9) may be declared, but they shall be declared when they are added to the product for purposes of supplementation, or when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (e.g., amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

(A) The names and the quantitative amounts by weight of each (b)(2)-dietary ingredient shall be presented under the heading ''Amount Per Serving.'' The heading may be centered over the column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. When the serving size of the product is one unit (e.g., one tablet), a heading consistent with the declaration of the serving size, such as ''Amount Per Tablet'' or ''Each Tablet Contains,'' may be used in place of the heading ''Amount Per Serving.'' Other appropriate terms, such as capsule, packet, or teaspoonful, also may be used in place of the term ''Serving.''

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutrition label in the order and manner of indentation specified in § 101.9(c) except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9.

(*1*) When ''Calories'' are declared, they shall be listed first in the column of names, beneath a light bar separating the heading ''Amount Per Serving'' from the list of names. When ''Calories from fat'' or ''Calories from saturated fat'' are declared, they shall be indented beneath ''Calories.''

(*2*) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B1), riboflavin (vitamin B2), folate (folacin or folic acid), and calories (energy). Energy content per serving may be expressed in kilojoules units, added in parentheses immediately following the statement of caloric content.

(*3*) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (e.g., ''Vitamin A (90% as beta-carotene)''). The amount of beta-carotene in terms of international units (IU) may be included in parentheses following the percent statement (e.g., ''Vitamin A (90% (4500 IU) as beta-carotene)'').

(ii) The number of calories, if declared, and the quantitative amount by weight per serving of each dietary ingredient required to be listed under paragraph (b)(2)(i) of this section shall be presented in a separate column aligned to the right of the column of names. The quantitative amounts by weight shall represent the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient (e.g., the weight of calcium rather than that of calcium carbonate).

(A) These amounts shall be expressed in the increments specified in § 101.9 (c)(1) through (c)(7), which includes increments for sodium and potassium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, shall be the actual amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg).

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed except that the percent for protein may be omitted as provided in § 101.9(c)(7), no percent shall be given for subcomponents for which DRV's have not been established (e.g., sugars), and, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, vitamin K, chloride, chromium, manganese, molybdenum, or selenium.

(A) When information on the percent of Daily Values is listed, this

information shall be presented in one column aligned under the heading of ''% Daily Value'' and to the right of the column of amounts. The headings ''% Daily Value (DV),'' ''% DV,'' ''Percent Daily Value,'' or ''Percent DV'' may be substituted for ''% Daily Value.'' The heading ''% Daily Value'' shall be placed on the same line as the heading ''Amount Per Serving.''

(B) The percent of Daily Value shall be calculated by dividing the quantitative amount by weight of each (b)(2)-dietary ingredient by the RDI as established in § 101.9(c)(8)(iv) or the DRV as established in § 101.9(c)(9) for the specified dietary ingredient and multiplying by 100, except that the percent of Daily Value for protein, when present, shall be calculated as specified in § 101.9(c)(7)(ii). The actual quantitative amount by weight of each dietary ingredient shall be used in this calculation, except that for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber, the percent shall be calculated by dividing either the quantitative amount by weight declared on the label or the actual amount (i.e., before rounding) by the DRV for the dietary ingredient. The numerical value shall be followed by the symbol for percent (i.e., %).

(C) The percentages based on RDI's and on DRV's shall be expressed to the nearest whole percent, except that for dietary ingredients for which DRV's have been established, ''Less than 1%'' or ''<1%'' shall be used to declare the ''% Daily Value'' when the quantitative amount of the dietary ingredient by weight is great enough to require that the dietary ingredient be listed, but the amount is so small that the ''% Daily Value'' when rounded to the nearest percent is zero (e.g., the percent Daily Value for 1 gram of total carbohydrate is to be listed as ''Less than 1%'' or ''<1%'').

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet.''

(E) The percent of Daily Value shall be based on RDI and DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(10)(ii) of this section.

(F) For declared subcomponents that have no DRV's and, on the labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less that 4 years of age, or pregnant or lactating women, for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, vitamin K, chloride, chromium, manganese, molybdenum, or selenium, a symbol (e.g., an asterisk) shall be placed in the ''Percent Daily Value'' column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by the statement ''Daily Value not established.''

(G) When calories, calories from fat, or calories from saturated fat are declared, the space under the ''% Daily Value'' column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the ''% Daily Value'' column, the column may be omitted as shown in paragraph (e)(10)(vii) of this section. When the ''% Daily Value'' column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under ''Amount Per Serving.''

(3) *Information on dietary ingredients for which RDI's and DRV's have not been established.* (i) Dietary ingredients for which FDA has not established an RDI or DRV and that are not subject to regulation under paragraph (b)(2) of this section (hereinafter referred to as ''other dietary ingredients'') shall be declared by their common or usual name when they are present in a dietary supplement, in a column that is under the column of names described in paragraph (b)(2)(i)(B) of this section and under the heavy bar described in paragraph (e)(6) of this section, except that if no (b)(2)-dietary ingredients are declared, other dietary ingredients shall be listed directly beneath the heading ''Amount Per Serving'' described in paragraph (b)(2)(i)(A).

(ii) The quantitative amount by weight per serving of other dietary ingredients shall be presented in a separate column aligned to the right of the column of names and underneath the column of amounts described in paragraph (b)(2)(ii) of this section. The quantitative amount by weight shall be the weight of the other dietary ingredient listed and not the weight of any component, or the source, of that dietary ingredient. These amounts shall be expressed using metric measures in appropriate units (i.e., 1,000 or more units shall be declared in the next higher set of units, e.g., 1,100 mg shall be declared as 1.1 g). For any dietary ingredients that are liquid extracts, the weight shall not include the weight of solvents.

(iii) Other dietary ingredients shall bear a symbol (e.g., an asterisk) in the column under the heading of ''% Daily Value'' that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement ''Daily Value not established,'' except that when the heading ''% Daily Value'' is not used, the symbol shall follow the quantitative amount by weight for each dietary ingredient listed.

(c) A proprietary blend of dietary ingredients shall be included in the list of dietary ingredients described in paragraph (b)(3)(i) of this section and identified by the term ''Proprietary Blend,'' which may be modified by an appropriate descriptive term or fanciful name. Except as specified in this paragraph, all other requirements for the listing of dietary ingredients in dietary supplements are applicable.

(1) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(2) of this section shall be declared in accordance with paragraph (b)(2) of this section.

(2) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(3) of this section (i.e., ''other dietary ingredients'') shall be declared in descending order of predominance by weight, in a column or linear fashion, and indented under the term ''Proprietary Blend.''

(3) The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend and shall be placed on the same line to the right of the term ''Proprietary Blend'' underneath the column of amounts described in paragraph (b)(2)(ii) of this section. A symbol (e.g., asterisk), which refers to the same symbol placed at the bottom of the nutrition label that is followed by the statement ''Daily Value not established,'' shall be placed under the heading ''% Daily Value,'' if present, or immediately following the quantitative amount by weight for the proprietary blend.

(4) The sample label shown in paragraph (e)(10)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

(d) The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words ''as'' or ''from'', e.g., ''Calcium (as calcium carbonate),'' except that manner of presentation is unnecessary when the name of the dietary ingredient (e.g., Siberian ginseng) or its synonym (e.g., ascorbic acid) is itself the source ingredient. When a source ingredient is identified in parentheses within the nutrition label, or when the name of the dietary ingredient or its synonym is the source ingredient, it shall not be required to be listed again in the ingredient statement that appears outside of the nutrition label. When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with § 101.4(g), which shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

(1) Source ingredients shall be identified in accordance with § 101.4 (i.e., shall be listed by common or usual name, and the listing of botanicals shall specify the Latin binomial name and the part of the plant from which the ingredient is derived) regardless of whether they are listed in an ingredient statement or in the nutrition label.

(2) When source ingredients are listed within the nutrition label, and two or more are used to provide a single dietary ingredient, all of the sources shall be listed within the parentheses in descending order by weight.

(3) Representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or in the ingredient list (e.g., ''Calcium (as calcium carbonate USP)'').

(e) Nutrition information specified in this section shall be presented as follows:

(1) The title, ''Supplement Facts,'' shall be set in a type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label. The title and all headings shall be bolded to distinguish them from other information.

(2) The nutrition information shall be enclosed in a box by using hairlines.

(3) All information within the nutrition label shall utilize:

(i) A single easy-to-read type style,

(ii) All black or one color type, printed on a white or other neutral contrasting background whenever practical,

(iii) Upper and lower case letters, except that all uppercase lettering may be utilized for packages that have a total surface area available to bear labeling of less than 12 square inches,

(iv) At least one point leading (i.e., space between lines of text), and

(v) Letters that do not touch.

(4) Except as provided for small and intermediate-sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (e.g., ''Amount Per Serving'' and ''% Daily Value'') and for footnotes (e.g., ''Percent Daily Values are based on a 2,000 calorie diet'').

(5) A hairline rule that is centered between the lines of text shall separate each dietary ingredient required in paragraph (b)(2) and (b)(3) of this section from the dietary ingredient above and beneath it, as shown in paragraph (e)(10) of this section.

(6) A heavy bar shall be placed:

(i) Beneath the subheading ''Servings Per Container'' except that if ''Servings Per Container'' is not required and, as a result, not declared, the bar shall be placed beneath the subheading ''Serving Size,''

(ii) Beneath the last dietary ingredient to be listed under paragraph (b)(2)(i) of this section, if any, and

(iii) Beneath the last other dietary ingredient to be listed under paragraph (b)(3) of this section, if any.

(7) A light bar shall be placed beneath the headings ''Amount Per Serving'' and ''% Daily Value.''

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(10)(iii) of this section.

(9) In the interest of uniformity of presentation, FDA urges that the information be presented using the graphic specifications set forth in Appendix B to part 101, as applicable.

(10) The following sample labels are presented for the purpose of illustration:

BILLING CODE 4160–01–P

(i) Multiple vitamins:

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benozate.

(ii) Multiple vitamins for children and adults:

Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B_6	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B_{12}	5 mcg	167%	83%

* Percent Daily Values are based on 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, vitamin E acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, and folic acid.

(iii) Multiple vitamins in packets:

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

	AM Packet		PM Packet	
Amount Per Serving		% Daily Value		% Daily Value
Vitamin A	2500 IU	50%	2500 IU	50%
Vitamin C	60 mg	100%	60 mg	100%
Vitamin D	400 IU	100%		
Vitamin E	30 IU	100%		
Thiamin	1.5 mg	100%	1.5 mg	100%
Riboflavin	1.7 mg	100%	1.7 mg	100%
Niacin	20 mg	100%	20 mg	100%
Vitamin B_6	2.0 mg	100%	2.0 mg	100%
Folate	200 mcg	50%	200 mcg	50%
Vitamin B_{12}	3 mcg	50%	3 mcg	50%
Biotin			30 mcg	10%
Pantothenic Acid	5 mg	50%	5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, niacinamide, vitamin E acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate. magnesium stearate, riboflavin, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, folic acid, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, vitamin D and vitamin B_{12}.

(iv) Dietary supplement containing dietary ingredient with and without RDI's and DRV's:

Supplement Facts

Serving Size 1 Capsule

	Amount Per Capsule	% Daily Value
Calories	20	
Calories from Fat	20	
Total Fat	2 g	3%*
Saturated Fat	0.5 g	3%*
Polyunsaturated Fat	1 g	†
Monounsaturated Fat	0.5 g	†
Vitamin A	4250 IU	85%
Vitamin D	425 IU	106%
Omega-3 fatty acids	0.5 g	†

* Percent Daily Values are based on 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod fish oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients:

Supplement Facts

Serving Size 1 tsp (2.7 g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	†
Chamomile, Hungarian (*Matricaria chamomillia* L.)(flower)		
Hyssop (*Hyssopus officinalis* L.)(leaves)		

* Percent Daily Values are based on 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	
Ginseng, powdered (*Panax ginseng* C. A. Mey.)(root)	250 mcg*

* Daily Value not established.

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids:

Supplement Facts

Serving size 1 Tablet

Amount Per Tablet	
Calories	15
L-isoleucine (as L-isoleucine hydrochloride)	450 mg*
L-leucine (as L-leucine hydrochloride)	620 mg*
L-lysine (as L-lysine hydrochloride)	500 mg*
L-methionine (as L-methionine hydrochloride)	350 mg*
L-cystine (as L-cystine hydrochloride)	200 mg*
L-phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
L-tryosine (as L-tryosine hydrochloride)	900 mg*
L-threonine (as L-threonine hydrochloride)	300 mg*
L-valine (as L-valine hydrochloride)	650 mg*

* Daily Value not established.

Other ingredients: Cellulose, lactose, and magnesium stearate.

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(11) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(10) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right shall be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

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Supplement Facts

Serving Size 1 Packet

Amount Per Packet		% Daily Value
Vitamin A (from fish liver oil)	5,000 IU	100%
Vitamin C (as ascorbic acid and from rose hips, *Rosa* L. spp.)(fruit)	250 mg	417%
Vitamin D	400 IU	100%
Vitamin E (as d-alpha tocopherol)	150 IU	500%
Thiamin (as thiamin mononitrate)	75 mg	5000%
Riboflavin	75 mg	4412%
Niacin (as niacinamide)	75 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	75 mg	3750%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	1667%
Biotin	100 mcg	33%
Pantothenic Acid	75 mg	750%
Calcium (from oystershell)	100 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%
Magnesium (as magnesium oxide)	60 mg	15%
Zinc (as zinc oxide)	15 mg	100%
Selenium (as sodium selenate)	25 mcg	36%
Copper (as cupric oxide)	1 mg	50%
Manganese (as manganese sulfate)	5 mg	143%
Chromium (as chromium chloride)	50 mcg	38%
Molybdenum (as sodium molybdate)	50 mcg	31%
Potassium (as potassium chloride)	10 mg	< 1%
Choline (as choline chloride)	100 mg	*
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
Rutin (from common buckwheat, *Polygonum fagopyrum* L.)(leaves)	25 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established

Other ingredients: Cellulose, stearic acid and silica.

(f)(1) Compliance with this section will be determined in accordance with § 101.9 (g)(1) through (g)(8). The criteria on class I and class II nutrients given in § 101.9 (g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses of these other dietary ingredients over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(g) Except as provided in paragraphs (i)(2) and (i)(5) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(h) Dietary supplements are subject to the exemptions specified in:

(1) § 101.9(j)(1) for dietary supplements that are offered for sale by a person who makes direct sales to consumers (i.e., a retailer) who has annual gross sales or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(2) § 101.9(j)(18) for dietary supplements that are low- volume products (that is, they meet the requirements for units sold in § 101.9(j)(18) (i) or (ii)) that, except as provided in § 101.9(j)(18)(iv), are the subject of a claim for an exemption that provides the information required under § 101.9(j)(18)(iv), that is filed before the beginning of the time period for which the exemption is claimed, and that is filed by a person that qualifies to claim the exemption under the requirements for average full-time equivalent employees in § 101.9(j)(18) (i) or (ii), and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(3) § 101.9(j)(9) for dietary supplements shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other dietary supplements or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(i) Dietary supplements are subject to the special labeling provisions specified in:

(1) § 101.9(j)(5)(i) for food, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age, in that nutrition labels on such foods shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol;

(2) § 101.9(j)(13) for foods in small or intermediate-sized packages, except that:

(i) All information within the nutrition label on small-sized packages, which have a total surface area available to labeling of less than 12 square inches, shall be in type size no smaller than 4.5 point;

(ii) All information within the nutrition label on intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, shall be in type size no smaller than 6 point, except that dietary supplements in which there are more than 8 dietary ingredients to be listed in the nutrition label, and that are in packages that have less than 20 square inches of surface area available to bear labeling, may use type size no smaller than 4.5 point when necessary.

(iii) When the nutrition information is presented on any panel under § 101.9(j)(13)(ii)(D), the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(iv) When it is not possible for a small or intermediate-sized package that is enclosed in an outer package to comply with these type size requirements, the type size of the nutrition label on the primary (inner) container may be as small as needed to accommodate all of the required label information provided that the primary container is securely enclosed in outer packaging, the nutrition labeling on the outer packaging meets the applicable type size requirements, and such outer packaging is not intended to be separated from the primary container under conditions of retail sale.

(3) § 101.9(j)(15) for foods in multiunit food containers;

(4) § 101.9(j)(16) for foods sold in bulk containers; and

(5) § 101.9(j)(17) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information, except that the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(j) Dietary supplements shall be subject to the misbranding provisions of § 101.9(k).

7. Section 101.65 is amended by revising paragraph (b)(4) to read as follows:

§ 101.65 Implied Nutrient Content Claims and Related Label Statements.

* * * * *

(b) * * *

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., ''corn oil,'' ''oat bran,'' ''dietary supplement of vitamin C 60 mg tablet'').

* * * * *

Dated: October 11, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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